

PROTOCOL No. PM-8450

REPORT No. 1148

Covance Study No. 12226-8450

DRAFT 1

Research Study Report

24 JULY 2002

VOL 25 of 25

Pgs. 14548 to 15132

PM3006629902

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 1 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.1: Since the last time you were interviewed, have you smoked any of the following? Manufactured cigarettes	001	F-S	Yes
	002	F-S	Yes
	003	F-S	Yes
	004	F-S	Yes
	005	F-S	Yes
	006	F-S	Yes
	007	F-S	Yes
	008	F-S	Yes
	009	F-S	Yes
	011	F-S	Yes
	012	F-S	Yes
	013	F-S	Yes
	014	F-S	Yes
	015	F-S	Yes
	016	F-S	Yes
	017	F-S	Yes
	018	F-S	Yes
	019	F-S	Yes
	020	F-S	Yes
	021	F-S	Yes
	022	F-S	Yes
	023	F-S	Yes
	024	F-S	Yes
	025	F-S	Yes
	026	F-S	Yes
	027	F-S	Yes
	028	F-S	Yes
	029	F-S	Yes
	030	F-S	Yes
	031	F-S	Yes
	032	F-S	Yes
	033	F-S	Yes
	034	F-S	Yes
	035	F-S	Yes
	036	M-S	Yes
	037	M-S	Yes

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629903

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 2 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.1: Since the last time you were interviewed, have you smoked any of the following? Manufactured cigarettes	038	M-S	Yes
	039	M-S	Yes
	040	M-S	Yes
	041	M-S	Yes
	042	M-S	Yes
	043	M-S	Yes
	044	M-S	Yes
	045	M-S	Yes
	046	M-S	Yes
	047	M-S	Yes
	048	M-S	Yes
	049	M-S	Yes
	050	M-S	Yes
	052	M-S	Yes
	054	M-S	No
	055	M-S	Yes
	056	M-S	Yes
	057	M-S	Yes
	058	M-S	Yes
	059	M-S	Yes
	060	M-S	Yes
	061	M-S	Yes
	062	M-S	Yes
	063	M-S	Yes
	065	M-S	Yes
	067	M-S	Yes
	068	M-S	Yes
	069	M-S	Yes
	071	F-NS	No
	072	F-NS	No
	073	F-NS	No
	074	F-NS	No
	075	F-NS	No
	076	F-NS	No
	077	F-NS	No
	078	F-NS	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629904

Draft 1: 24 July 2002

Page 14549 of 15132

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 3 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.1: Since the last time you were interviewed, have you smoked any of the following? Manufactured cigarettes	079	F-NS	No
	080	F-NS	No
	081	F-NS	No
	082	F-NS	No
	083	F-NS	No
	084	F-NS	No
	085	F-NS	No
	086	F-NS	No
	087	F-NS	No
	088	F-NS	No
	089	F-NS	No
	090	F-NS	No
	091	F-NS	No
	092	F-NS	No
	093	F-NS	No
	094	F-NS	No
	095	F-NS	No
	096	F-NS	No
	097	F-NS	No
	098	F-NS	No
	099	F-NS	No
	100	F-NS	No
	101	F-NS	No
	102	F-NS	No
	103	F-NS	No
	104	M-NS	No
	105	M-NS	No
	106	M-NS	No
	107	M-NS	No
	108	M-NS	No
	109	M-NS	No
	110	M-NS	No
	111	M-NS	No
	112	M-NS	No
	114	M-NS	No
	115	M-NS	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 4 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.1: Since the last time you were interviewed, have you smoked any of the following? Manufactured cigarettes	116	M-NS	No
	117	M-NS	No
	118	M-NS	No
	119	M-NS	No
	120	M-NS	No
	121	M-NS	No
	122	M-NS	No
	123	M-NS	No
	124	M-NS	No
	125	M-NS	No
	126	M-NS	No
	127	M-NS	No
	128	M-NS	No
	129	M-NS	No
	130	M-NS	No
	131	M-NS	No
	132	M-NS	No
	133	M-NS	No
	134	M-NS	No
	135	M-NS	No
	500	F-NS	No
	501	F-NS	No
	502	F-S	Yes
	503	F-S	Yes
	504	F-S	Yes
	505	F-NS	No
	506	F-S	Yes
Cigars	001	F-S	No
	002	F-S	No
	003	F-S	No
	004	F-S	No
	005	F-S	No
	006	F-S	No
	007	F-S	No
	008	F-S	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 5 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.1: Since the last time you were interviewed, have you smoked any of the following? Cigars	009	F-S	No
	011	F-S	No
	012	F-S	No
	013	F-S	No
	014	F-S	No
	015	F-S	No
	016	F-S	No
	017	F-S	No
	018	F-S	No
	019	F-S	No
	020	F-S	No
	021	F-S	No
	022	F-S	No
	023	F-S	No
	024	F-S	No
	025	F-S	No
	026	F-S	No
	027	F-S	No
	028	F-S	No
	029	F-S	No
	030	F-S	No
	031	F-S	No
	032	F-S	No
	033	F-S	No
	034	F-S	No
	035	F-S	No
	036	M-S	No
	037	M-S	No
	038	M-S	No
	039	M-S	No
	040	M-S	No
	041	M-S	No
	042	M-S	No
	043	M-S	No
	044	M-S	No
	045	M-S	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629907

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 6 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.1: Since the last time you were interviewed, have you smoked any of the following? Cigars	046	M-S	No
	047	M-S	No
	048	M-S	No
	049	M-S	No
	050	M-S	No
	052	M-S	No
	054	M-S	No
	055	M-S	No
	056	M-S	No
	057	M-S	No
	058	M-S	No
	059	M-S	No
	060	M-S	No
	061	M-S	No
	062	M-S	No
	063	M-S	No
	065	M-S	No
	067	M-S	No
	068	M-S	No
	069	M-S	No
	071	F-NS	No
	072	F-NS	No
	073	F-NS	No
	074	F-NS	No
	075	F-NS	No
	076	F-NS	No
	077	F-NS	No
	078	F-NS	No
	079	F-NS	No
	080	F-NS	No
	081	F-NS	No
	082	F-NS	No
	083	F-NS	No
	084	F-NS	No
	085	F-NS	No
	086	F-NS	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 7 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.1: Since the last time you were interviewed, have you smoked any of the following? Cigars	087	F-NS	No
	088	F-NS	No
	089	F-NS	No
	090	F-NS	No
	091	F-NS	No
	092	F-NS	No
	093	F-NS	No
	094	F-NS	No
	095	F-NS	No
	096	F-NS	No
	097	F-NS	No
	098	F-NS	No
	099	F-NS	No
	100	F-NS	No
	101	F-NS	No
	102	F-NS	No
	103	F-NS	No
	104	M-NS	No
	105	M-NS	No
	106	M-NS	No
	107	M-NS	No
	108	M-NS	No
	109	M-NS	No
	110	M-NS	No
	111	M-NS	No
	112	M-NS	No
	114	M-NS	No
	115	M-NS	No
	116	M-NS	No
	117	M-NS	No
	118	M-NS	No
	119	M-NS	No
	120	M-NS	No
	121	M-NS	No
	122	M-NS	No
	123	M-NS	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629909

Draft 1: 24 July 2002

Page 14554 of 15132

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 8 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.1: Since the last time you were interviewed, have you smoked any of the following? Cigars	124	M-NS	No
	125	M-NS	No
	126	M-NS	No
	127	M-NS	No
	128	M-NS	No
	129	M-NS	No
	130	M-NS	No
	131	M-NS	No
	132	M-NS	No
	133	M-NS	No
	134	M-NS	No
	135	M-NS	No
	500	F-NS	No
	501	F-NS	No
	502	F-S	No
	503	F-S	No
	504	F-S	No
	505	F-NS	No
	506	F-S	No
Cigarillos	001	F-S	No
	002	F-S	No
	003	F-S	No
	004	F-S	No
	005	F-S	No
	006	F-S	No
	007	F-S	No
	008	F-S	No
	009	F-S	No
	011	F-S	No
	012	F-S	No
	013	F-S	No
	014	F-S	No
	015	F-S	No
	016	F-S	No
	017	F-S	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629910

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 9 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.1: Since the last time you were interviewed, have you smoked any of the following? Cigarillos	018	F-S	No
	019	F-S	No
	020	F-S	No
	021	F-S	No
	022	F-S	No
	023	F-S	No
	024	F-S	No
	025	F-S	No
	026	F-S	No
	027	F-S	No
	028	F-S	No
	029	F-S	No
	030	F-S	No
	031	F-S	No
	032	F-S	No
	033	F-S	No
	034	F-S	No
	035	F-S	No
	036	M-S	No
	037	M-S	No
	038	M-S	No
	039	M-S	No
	040	M-S	No
	041	M-S	No
	042	M-S	No
	043	M-S	No
	044	M-S	No
	045	M-S	No
	046	M-S	No
	047	M-S	No
	048	M-S	No
	049	M-S	No
	050	M-S	No
	052	M-S	No
	054	M-S	No
	055	M-S	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 10 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.1: Since the last time you were interviewed, have you smoked any of the following? Cigarillos	056	M-S	No
	057	M-S	No
	058	M-S	No
	059	M-S	No
	060	M-S	No
	061	M-S	No
	062	M-S	No
	063	M-S	No
	065	M-S	No
	067	M-S	No
	068	M-S	No
	069	M-S	No
	071	F-NS	No
	072	F-NS	No
	073	F-NS	No
	074	F-NS	No
	075	F-NS	No
	076	F-NS	No
	077	F-NS	No
	078	F-NS	No
	079	F-NS	No
	080	F-NS	No
	081	F-NS	No
	082	F-NS	No
	083	F-NS	No
	084	F-NS	No
	085	F-NS	No
	086	F-NS	No
	087	F-NS	No
	088	F-NS	No
	089	F-NS	No
	090	F-NS	No
	091	F-NS	No
	092	F-NS	No
	093	F-NS	No
	094	F-NS	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 11 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.1: Since the last time you were interviewed, have you smoked any of the following? Cigarillos	095	F-NS	No
	096	F-NS	No
	097	F-NS	No
	098	F-NS	No
	099	F-NS	No
	100	F-NS	No
	101	F-NS	No
	102	F-NS	No
	103	F-NS	No
	104	M-NS	No
	105	M-NS	No
	106	M-NS	No
	107	M-NS	No
	108	M-NS	No
	109	M-NS	No
	110	M-NS	No
	111	M-NS	No
	112	M-NS	No
	114	M-NS	No
	115	M-NS	No
	116	M-NS	No
	117	M-NS	No
	118	M-NS	No
	119	M-NS	No
	120	M-NS	No
	121	M-NS	No
	122	M-NS	No
	123	M-NS	No
	124	M-NS	No
	125	M-NS	No
	126	M-NS	No
	127	M-NS	No
	128	M-NS	No
	129	M-NS	No
	130	M-NS	No
	131	M-NS	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629913

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 12 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.1: Since the last time you were interviewed, have you smoked any of the following? Cigarillos	132	M-NS	No
	133	M-NS	No
	134	M-NS	No
	135	M-NS	No
	500	F-NS	No
	501	F-NS	No
	502	F-S	No
	503	F-S	No
	504	F-S	No
	505	F-NS	No
	506	F-S	No
Pipe	001	F-S	No
	002	F-S	No
	003	F-S	No
	004	F-S	No
	005	F-S	No
	006	F-S	No
	007	F-S	No
	008	F-S	No
	009	F-S	No
	011	F-S	No
	012	F-S	No
	013	F-S	No
	014	F-S	No
	015	F-S	No
	016	F-S	No
	017	F-S	No
	018	F-S	No
	019	F-S	No
	020	F-S	No
	021	F-S	No
	022	F-S	No
	023	F-S	No
	024	F-S	No
	025	F-S	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 13 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.1: Since the last time you were interviewed, have you smoked any of the following? Pipe	026	F-S	No
	027	F-S	No
	028	F-S	No
	029	F-S	No
	030	F-S	No
	031	F-S	No
	032	F-S	No
	033	F-S	No
	034	F-S	No
	035	F-S	No
	036	M-S	No
	037	M-S	No
	038	M-S	No
	039	M-S	No
	040	M-S	No
	041	M-S	No
	042	M-S	No
	043	M-S	No
	044	M-S	No
	045	M-S	No
	046	M-S	No
	047	M-S	No
	048	M-S	No
	049	M-S	No
	050	M-S	No
	052	M-S	No
	054	M-S	No
	055	M-S	No
	056	M-S	No
	057	M-S	No
	058	M-S	No
	059	M-S	No
	060	M-S	No
	061	M-S	No
	062	M-S	No
	063	M-S	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 14 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.1: Since the last time you were interviewed, have you smoked any of the following? Pipe	065	M-S	No
	067	M-S	No
	068	M-S	No
	069	M-S	No
	071	F-NS	No
	072	F-NS	No
	073	F-NS	No
	074	F-NS	No
	075	F-NS	No
	076	F-NS	No
	077	F-NS	No
	078	F-NS	No
	079	F-NS	No
	080	F-NS	No
	081	F-NS	No
	082	F-NS	No
	083	F-NS	No
	084	F-NS	No
	085	F-NS	No
	086	F-NS	No
	087	F-NS	No
	088	F-NS	No
	089	F-NS	No
	090	F-NS	No
	091	F-NS	No
	092	F-NS	No
	093	F-NS	No
	094	F-NS	No
	095	F-NS	No
	096	F-NS	No
	097	F-NS	No
	098	F-NS	No
	099	F-NS	No
	100	F-NS	No
	101	F-NS	No
	102	F-NS	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629916

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 15 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.1: Since the last time you were interviewed, have you smoked any of the following? Pipe	103	F-NS	No
	104	M-NS	No
	105	M-NS	No
	106	M-NS	No
	107	M-NS	No
	108	M-NS	No
	109	M-NS	No
	110	M-NS	No
	111	M-NS	No
	112	M-NS	No
	114	M-NS	No
	115	M-NS	No
	116	M-NS	No
	117	M-NS	No
	118	M-NS	No
	119	M-NS	No
	120	M-NS	No
	121	M-NS	No
	122	M-NS	No
	123	M-NS	No
	124	M-NS	No
	125	M-NS	No
	126	M-NS	No
	127	M-NS	No
	128	M-NS	No
	129	M-NS	No
	130	M-NS	No
	131	M-NS	No
	132	M-NS	No
	133	M-NS	No
	134	M-NS	No
	135	M-NS	No
	500	F-NS	No
	501	F-NS	No
	502	F-S	No
	503	F-S	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629917

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 16 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.1: Since the last time you were interviewed, have you smoked any of the following? Pipe	504	F-S	No
	505	F-NS	No
	506	F-S	No
Other	001	F-S	No
	002	F-S	No
	003	F-S	No
	004	F-S	No
	005	F-S	No
	006	F-S	No
	007	F-S	No
	008	F-S	No
	009	F-S	No
	011	F-S	No
	012	F-S	No
	013	F-S	No
	014	F-S	No
	015	F-S	No
	016	F-S	No
	017	F-S	No
	018	F-S	No
	019	F-S	No
	020	F-S	No
	021	F-S	No
	022	F-S	No
	023	F-S	No
	024	F-S	No
	025	F-S	No
	026	F-S	No
	027	F-S	No
	028	F-S	No
	029	F-S	No
	030	F-S	No
	031	F-S	No
	032	F-S	No
	033	F-S	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 17 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.1: Since the last time you were interviewed, have you smoked any of the following? Other	034	F-S	No
	035	F-S	No
	036	M-S	No
	037	M-S	No
	038	M-S	No
	039	M-S	No
	040	M-S	No
	041	M-S	No
	042	M-S	No
	043	M-S	No
	044	M-S	No
	045	M-S	No
	046	M-S	No
	047	M-S	No
	048	M-S	No
	049	M-S	No
	050	M-S	No
	052	M-S	No
	054	M-S	No
	055	M-S	No
	056	M-S	No
	057	M-S	No
	058	M-S	No
	059	M-S	No
	060	M-S	No
	061	M-S	No
	062	M-S	No
	063	M-S	No
	065	M-S	No
	067	M-S	No
	068	M-S	No
	069	M-S	No
	071	F-NS	No
	072	F-NS	No
	073	F-NS	No
	074	F-NS	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 18 of 111)

Question	Subject Number	Subject Classification*	Response
A.1: Since the last time you were interviewed, have you smoked any of the following? Other	075	F-NS	No
	076	F-NS	No
	077	F-NS	No
	078	F-NS	No
	079	F-NS	No
	080	F-NS	No
	081	F-NS	No
	082	F-NS	No
	083	F-NS	No
	084	F-NS	No
	085	F-NS	No
	086	F-NS	No
	087	F-NS	No
	088	F-NS	No
	089	F-NS	No
	090	F-NS	No
	091	F-NS	No
	092	F-NS	No
	093	F-NS	No
	094	F-NS	No
	095	F-NS	No
	096	F-NS	No
	097	F-NS	No
	098	F-NS	No
	099	F-NS	No
	100	F-NS	No
	101	F-NS	No
	102	F-NS	No
	103	F-NS	No
	104	M-NS	No
	105	M-NS	No
	106	M-NS	No
	107	M-NS	No
	108	M-NS	No
	109	M-NS	No
	110	M-NS	No

* Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629920

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 19 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.1: Since the last time you were interviewed, have you smoked any of the following? Other	111	M-NS	No
	112	M-NS	No
	114	M-NS	No
	115	M-NS	No
	116	M-NS	No
	117	M-NS	No
	118	M-NS	No
	119	M-NS	No
	120	M-NS	No
	121	M-NS	No
	122	M-NS	No
	123	M-NS	No
	124	M-NS	No
	125	M-NS	No
	126	M-NS	No
	127	M-NS	No
	128	M-NS	No
	129	M-NS	No
	130	M-NS	No
	131	M-NS	No
	132	M-NS	No
	133	M-NS	No
	134	M-NS	No
	135	M-NS	No
	500	F-NS	No
	501	F-NS	No
	502	F-S	No
	503	F-S	No
	504	F-S	No
	505	F-NS	No
	506	F-S	No
A.2: Since the last time you were interviewed, have you used any of the following nicotine-containing products? Snuff	001	F-S	No
	002	F-S	No
	003	F-S	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629921

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 20 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.2: Since the last time you were interviewed, have you used any of the following nicotine-containing products? Snuff	004	F-S	No
	005	F-S	No
	006	F-S	No
	007	F-S	No
	008	F-S	No
	009	F-S	No
	011	F-S	No
	012	F-S	No
	013	F-S	No
	014	F-S	No
	015	F-S	No
	016	F-S	No
	017	F-S	No
	018	F-S	No
	019	F-S	No
	020	F-S	No
	021	F-S	No
	022	F-S	No
	023	F-S	No
	024	F-S	No
	025	F-S	No
	026	F-S	No
	027	F-S	No
	028	F-S	No
	029	F-S	No
	030	F-S	No
	031	F-S	No
	032	F-S	No
	033	F-S	No
	034	F-S	No
	035	F-S	No
	036	M-S	No
	037	M-S	No
	038	M-S	No
	039	M-S	No
	040	M-S	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 21 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.2: Since the last time you were interviewed, have you used any of the following nicotine-containing products? Snuff	041	M-S	No
	042	M-S	No
	043	M-S	No
	044	M-S	No
	045	M-S	No
	046	M-S	No
	047	M-S	No
	048	M-S	No
	049	M-S	No
	050	M-S	No
	052	M-S	No
	054	M-S	No
	055	M-S	No
	056	M-S	No
	057	M-S	No
	058	M-S	No
	059	M-S	No
	060	M-S	No
	061	M-S	No
	062	M-S	No
	063	M-S	No
	065	M-S	No
	067	M-S	No
	068	M-S	No
	069	M-S	No
	071	F-NS	No
	072	F-NS	No
	073	F-NS	No
	074	F-NS	No
	075	F-NS	No
	076	F-NS	No
	077	F-NS	No
	078	F-NS	No
	079	F-NS	No
	080	F-NS	No
	081	F-NS	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629923

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 22 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.2: Since the last time you were interviewed, have you used any of the following nicotine-containing products?			
Snuff	082	F-NS	No
	083	F-NS	No
	084	F-NS	No
	085	F-NS	No
	086	F-NS	No
	087	F-NS	No
	088	F-NS	No
	089	F-NS	No
	090	F-NS	No
	091	F-NS	No
	092	F-NS	No
	093	F-NS	No
	094	F-NS	No
	095	F-NS	No
	096	F-NS	No
	097	F-NS	No
	098	F-NS	No
	099	F-NS	No
	100	F-NS	No
	101	F-NS	No
	102	F-NS	No
	103	F-NS	No
	104	M-NS	No
	105	M-NS	No
	106	M-NS	No
	107	M-NS	No
	108	M-NS	No
	109	M-NS	No
	110	M-NS	No
	111	M-NS	No
	112	M-NS	No
	114	M-NS	No
	115	M-NS	No
	116	M-NS	No
	117	M-NS	No
	118	M-NS	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 23 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.2: Since the last time you were interviewed, have you used any of the following nicotine-containing products? Snuff	119	M-NS	No
	120	M-NS	No
	121	M-NS	No
	122	M-NS	No
	123	M-NS	No
	124	M-NS	No
	125	M-NS	No
	126	M-NS	No
	127	M-NS	No
	128	M-NS	No
	129	M-NS	No
	130	M-NS	No
	131	M-NS	No
	132	M-NS	No
	133	M-NS	No
	134	M-NS	No
	135	M-NS	No
	500	F-NS	No
	501	F-NS	No
	502	F-S	No
	503	F-S	No
	504	F-S	No
	505	F-NS	No
	506	F-S	No
Chewing Tobacco	001	F-S	No
	002	F-S	No
	003	F-S	No
	004	F-S	No
	005	F-S	No
	006	F-S	No
	007	F-S	No
	008	F-S	No
	009	F-S	No
	011	F-S	No
	012	F-S	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629925

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 24 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.2: Since the last time you were interviewed, have you used any of the following nicotine-containing products? Chewing Tobacco	013	F-S	No
	014	F-S	No
	015	F-S	No
	016	F-S	No
	017	F-S	No
	018	F-S	No
	019	F-S	No
	020	F-S	No
	021	F-S	No
	022	F-S	No
	023	F-S	No
	024	F-S	No
	025	F-S	No
	026	F-S	No
	027	F-S	No
	028	F-S	No
	029	F-S	No
	030	F-S	No
	031	F-S	No
	032	F-S	No
	033	F-S	No
	034	F-S	No
	035	F-S	No
	036	M-S	No
	037	M-S	No
	038	M-S	No
	039	M-S	No
	040	M-S	No
	041	M-S	No
	042	M-S	No
	043	M-S	No
	044	M-S	No
	045	M-S	No
	046	M-S	No
	047	M-S	Yes
	048	M-S	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629926

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 25 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.2: Since the last time you were interviewed, have you used any of the following nicotine-containing products? Chewing Tobacco	049	M-S	No
	050	M-S	No
	052	M-S	No
	054	M-S	No
	055	M-S	No
	056	M-S	No
	057	M-S	No
	058	M-S	No
	059	M-S	No
	060	M-S	No
	061	M-S	No
	062	M-S	No
	063	M-S	No
	065	M-S	No
	067	M-S	No
	068	M-S	No
	069	M-S	No
	071	F-NS	No
	072	F-NS	No
	073	F-NS	No
	074	F-NS	No
	075	F-NS	No
	076	F-NS	No
	077	F-NS	No
	078	F-NS	No
	079	F-NS	No
	080	F-NS	No
	081	F-NS	No
	082	F-NS	No
	083	F-NS	No
	084	F-NS	No
	085	F-NS	No
	086	F-NS	No
	087	F-NS	No
	088	F-NS	No
	089	F-NS	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629927

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 26 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.2: Since the last time you were interviewed, have you used any of the following nicotine-containing products? Chewing Tobacco	090	F-NS	No
	091	F-NS	No
	092	F-NS	No
	093	F-NS	No
	094	F-NS	No
	095	F-NS	No
	096	F-NS	No
	097	F-NS	No
	098	F-NS	No
	099	F-NS	No
	100	F-NS	No
	101	F-NS	No
	102	F-NS	No
	103	F-NS	No
	104	M-NS	No
	105	M-NS	No
	106	M-NS	No
	107	M-NS	No
	108	M-NS	No
	109	M-NS	No
	110	M-NS	No
	111	M-NS	No
	112	M-NS	No
	114	M-NS	No
	115	M-NS	No
	116	M-NS	No
	117	M-NS	No
	118	M-NS	No
	119	M-NS	No
	120	M-NS	No
	121	M-NS	No
	122	M-NS	No
	123	M-NS	No
	124	M-NS	No
	125	M-NS	No
	126	M-NS	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629928

Draft 1: 24 July 2002

Page 14573 of 15132

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 27 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.2: Since the last time you were interviewed, have you used any of the following nicotine-containing products? Chewing Tobacco	127	M-NS	No
	128	M-NS	No
	129	M-NS	No
	130	M-NS	No
	131	M-NS	No
	132	M-NS	No
	133	M-NS	No
	134	M-NS	No
	135	M-NS	No
	500	F-NS	No
	501	F-NS	No
	502	F-S	No
	503	F-S	No
	504	F-S	No
	505	F-NS	No
	506	F-S	No
Nicotine gum or lozenges	001	F-S	No
	002	F-S	No
	003	F-S	No
	004	F-S	No
	005	F-S	No
	006	F-S	No
	007	F-S	No
	008	F-S	No
	009	F-S	No
	011	F-S	No
	012	F-S	No
	013	F-S	No
	014	F-S	No
	015	F-S	No
	016	F-S	No
	017	F-S	No
	018	F-S	No
	019	F-S	No
	020	F-S	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629929

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 28 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.2: Since the last time you were interviewed, have you used any of the following nicotine-containing products? Nicotine gum or lozenges	021	F-S	No
	022	F-S	No
	023	F-S	No
	024	F-S	No
	025	F-S	No
	026	F-S	No
	027	F-S	No
	028	F-S	No
	029	F-S	No
	030	F-S	No
	031	F-S	No
	032	F-S	No
	033	F-S	No
	034	F-S	No
	035	F-S	No
	036	M-S	No
	037	M-S	No
	038	M-S	No
	039	M-S	No
	040	M-S	No
	041	M-S	No
	042	M-S	No
	043	M-S	No
	044	M-S	No
	045	M-S	No
	046	M-S	No
	047	M-S	No
	048	M-S	No
	049	M-S	No
	050	M-S	No
	052	M-S	No
	054	M-S	No
	055	M-S	No
	056	M-S	No
	057	M-S	No
	058	M-S	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629930

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 29 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.2: Since the last time you were interviewed, have you used any of the following nicotine-containing products? Nicotine gum or lozenges	059	M-S	No
	060	M-S	No
	061	M-S	No
	062	M-S	No
	063	M-S	No
	065	M-S	No
	067	M-S	No
	068	M-S	No
	069	M-S	No
	071	F-NS	No
	072	F-NS	No
	073	F-NS	No
	074	F-NS	No
	075	F-NS	No
	076	F-NS	No
	077	F-NS	No
	078	F-NS	No
	079	F-NS	No
	080	F-NS	No
	081	F-NS	No
	082	F-NS	No
	083	F-NS	No
	084	F-NS	No
	085	F-NS	No
	086	F-NS	No
	087	F-NS	No
	088	F-NS	No
	089	F-NS	No
	090	F-NS	No
	091	F-NS	No
	092	F-NS	No
	093	F-NS	No
	094	F-NS	No
	095	F-NS	No
	096	F-NS	No
	097	F-NS	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629931

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 30 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.2: Since the last time you were interviewed, have you used any of the following nicotine-containing products? Nicotine gum or lozenges	098	F-NS	No
	099	F-NS	No
	100	F-NS	No
	101	F-NS	No
	102	F-NS	No
	103	F-NS	No
	104	M-NS	No
	105	M-NS	No
	106	M-NS	No
	107	M-NS	No
	108	M-NS	No
	109	M-NS	No
	110	M-NS	No
	111	M-NS	No
	112	M-NS	No
	114	M-NS	No
	115	M-NS	No
	116	M-NS	No
	117	M-NS	No
	118	M-NS	No
	119	M-NS	No
	120	M-NS	No
	121	M-NS	No
	122	M-NS	No
	123	M-NS	No
	124	M-NS	No
	125	M-NS	No
	126	M-NS	No
	127	M-NS	No
	128	M-NS	No
	129	M-NS	No
	130	M-NS	No
	131	M-NS	No
	132	M-NS	No
	133	M-NS	No
	134	M-NS	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629932

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 31 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.2: Since the last time you were interviewed, have you used any of the following nicotine-containing products?			
Nicotine gum or lozenges	135	M-NS	No
	500	F-NS	No
	501	F-NS	No
	502	F-S	No
	503	F-S	No
	504	F-S	No
	505	F-NS	No
	506	F-S	No
Nicotine inhalers	001	F-S	No
	002	F-S	No
	003	F-S	No
	004	F-S	No
	005	F-S	No
	006	F-S	No
	007	F-S	No
	008	F-S	No
	009	F-S	No
	011	F-S	No
	012	F-S	No
	013	F-S	No
	014	F-S	No
	015	F-S	No
	016	F-S	No
	017	F-S	No
	018	F-S	No
	019	F-S	No
	020	F-S	No
	021	F-S	No
	022	F-S	No
	023	F-S	No
	024	F-S	No
	025	F-S	No
	026	F-S	No
	027	F-S	No
	028	F-S	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 32 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.2: Since the last time you were interviewed, have you used any of the following nicotine-containing products? Nicotine inhalers	029	F-S	No
	030	F-S	No
	031	F-S	No
	032	F-S	No
	033	F-S	No
	034	F-S	No
	035	F-S	No
	036	M-S	No
	037	M-S	No
	038	M-S	No
	039	M-S	No
	040	M-S	No
	041	M-S	No
	042	M-S	No
	043	M-S	No
	044	M-S	No
	045	M-S	No
	046	M-S	No
	047	M-S	No
	048	M-S	No
	049	M-S	No
	050	M-S	No
	052	M-S	No
	054	M-S	No
	055	M-S	No
	056	M-S	No
	057	M-S	No
	058	M-S	No
	059	M-S	No
	060	M-S	No
	061	M-S	No
	062	M-S	No
	063	M-S	No
	065	M-S	No
	067	M-S	No
	068	M-S	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629934

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 33 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.2: Since the last time you were interviewed, have you used any of the following nicotine-containing products?			
Nicotine inhalers	069	M-S	No
	071	F-NS	No
	072	F-NS	No
	073	F-NS	No
	074	F-NS	No
	075	F-NS	No
	076	F-NS	No
	077	F-NS	No
	078	F-NS	No
	079	F-NS	No
	080	F-NS	No
	081	F-NS	No
	082	F-NS	No
	083	F-NS	No
	084	F-NS	No
	085	F-NS	No
	086	F-NS	No
	087	F-NS	No
	088	F-NS	No
	089	F-NS	No
	090	F-NS	No
	091	F-NS	No
	092	F-NS	No
	093	F-NS	No
	094	F-NS	No
	095	F-NS	No
	096	F-NS	No
	097	F-NS	No
	098	F-NS	No
	099	F-NS	No
	100	F-NS	No
	101	F-NS	No
	102	F-NS	No
	103	F-NS	No
	104	M-NS	No
	105	M-NS	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 34 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.2: Since the last time you were interviewed, have you used any of the following nicotine-containing products? Nicotine inhalers	106	M-NS	No
	107	M-NS	No
	108	M-NS	No
	109	M-NS	No
	110	M-NS	No
	111	M-NS	No
	112	M-NS	No
	114	M-NS	No
	115	M-NS	No
	116	M-NS	No
	117	M-NS	No
	118	M-NS	No
	119	M-NS	No
	120	M-NS	No
	121	M-NS	No
	122	M-NS	No
	123	M-NS	No
	124	M-NS	No
	125	M-NS	No
	126	M-NS	No
	127	M-NS	No
	128	M-NS	No
	129	M-NS	No
	130	M-NS	No
	131	M-NS	No
	132	M-NS	No
	133	M-NS	No
	134	M-NS	No
	135	M-NS	No
	500	F-NS	No
	501	F-NS	No
	502	F-S	No
	503	F-S	No
	504	F-S	No
	505	F-NS	No
	506	F-S	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629936

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 35 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.2: Since the last time you were interviewed, have you used any of the following nicotine-containing products?			
Nicotine Patches	001	F-S	No
	002	F-S	No
	003	F-S	No
	004	F-S	No
	005	F-S	No
	006	F-S	No
	007	F-S	No
	008	F-S	No
	009	F-S	No
	011	F-S	No
	012	F-S	No
	013	F-S	No
	014	F-S	No
	015	F-S	No
	016	F-S	No
	017	F-S	No
	018	F-S	No
	019	F-S	No
	020	F-S	No
	021	F-S	No
	022	F-S	No
	023	F-S	No
	024	F-S	No
	025	F-S	No
	026	F-S	No
	027	F-S	No
	028	F-S	No
	029	F-S	No
	030	F-S	No
	031	F-S	No
	032	F-S	No
	033	F-S	No
	034	F-S	No
	035	F-S	No
	036	M-S	No
	037	M-S	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 36 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.2: Since the last time you were interviewed, have you used any of the following nicotine-containing products? Nicotine Patches	038	M-S	No
	039	M-S	No
	040	M-S	No
	041	M-S	No
	042	M-S	No
	043	M-S	No
	044	M-S	No
	045	M-S	No
	046	M-S	No
	047	M-S	No
	048	M-S	No
	049	M-S	No
	050	M-S	No
	052	M-S	No
	054	M-S	No
	055	M-S	No
	056	M-S	No
	057	M-S	No
	058	M-S	No
	059	M-S	No
	060	M-S	No
	061	M-S	No
	062	M-S	No
	063	M-S	No
	065	M-S	No
	067	M-S	No
	068	M-S	No
	069	M-S	No
	071	F-NS	No
	072	F-NS	No
	073	F-NS	No
	074	F-NS	No
	075	F-NS	No
	076	F-NS	No
	077	F-NS	No
	078	F-NS	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 37 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.2: Since the last time you were interviewed, have you used any of the following nicotine-containing products? Nicotine Patches	079	F-NS	No
	080	F-NS	No
	081	F-NS	No
	082	F-NS	No
	083	F-NS	No
	084	F-NS	No
	085	F-NS	No
	086	F-NS	No
	087	F-NS	No
	088	F-NS	No
	089	F-NS	No
	090	F-NS	No
	091	F-NS	No
	092	F-NS	No
	093	F-NS	No
	094	F-NS	No
	095	F-NS	No
	096	F-NS	No
	097	F-NS	No
	098	F-NS	No
	099	F-NS	No
	100	F-NS	No
	101	F-NS	No
	102	F-NS	No
	103	F-NS	No
	104	M-NS	No
	105	M-NS	No
	106	M-NS	No
	107	M-NS	No
	108	M-NS	No
	109	M-NS	No
	110	M-NS	No
	111	M-NS	No
	112	M-NS	No
	114	M-NS	No
	115	M-NS	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 38 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.2: Since the last time you were interviewed, have you used any of the following nicotine-containing products? Nicotine Patches	116	M-NS	No
	117	M-NS	No
	118	M-NS	No
	119	M-NS	No
	120	M-NS	No
	121	M-NS	No
	122	M-NS	No
	123	M-NS	No
	124	M-NS	No
	125	M-NS	No
	126	M-NS	No
	127	M-NS	No
	128	M-NS	No
	129	M-NS	No
	130	M-NS	No
	131	M-NS	No
	132	M-NS	No
	133	M-NS	No
	134	M-NS	No
	135	M-NS	No
	500	F-NS	No
	501	F-NS	No
	502	F-S	No
	503	F-S	No
	504	F-S	No
	505	F-NS	No
	506	F-S	No
Nicotine Sprays	001	F-S	No
	002	F-S	No
	003	F-S	No
	004	F-S	No
	005	F-S	No
	006	F-S	No
	007	F-S	No
	008	F-S	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629940

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 39 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.2: Since the last time you were interviewed, have you used any of the following nicotine-containing products?			
Nicotine Sprays	009	F-S	No
	011	F-S	No
	012	F-S	No
	013	F-S	No
	014	F-S	No
	015	F-S	No
	016	F-S	No
	017	F-S	No
	018	F-S	No
	019	F-S	No
	020	F-S	No
	021	F-S	No
	022	F-S	No
	023	F-S	No
	024	F-S	No
	025	F-S	No
	026	F-S	No
	027	F-S	No
	028	F-S	No
	029	F-S	No
	030	F-S	No
	031	F-S	No
	032	F-S	No
	033	F-S	No
	034	F-S	No
	035	F-S	No
	036	M-S	No
	037	M-S	No
	038	M-S	No
	039	M-S	No
	040	M-S	No
	041	M-S	No
	042	M-S	No
	043	M-S	No
	044	M-S	No
	045	M-S	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 40 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.2: Since the last time you were interviewed, have you used any of the following nicotine-containing products? Nicotine Sprays	046	M-S	No
	047	M-S	No
	048	M-S	No
	049	M-S	No
	050	M-S	No
	052	M-S	No
	054	M-S	No
	055	M-S	No
	056	M-S	No
	057	M-S	No
	058	M-S	No
	059	M-S	No
	060	M-S	No
	061	M-S	No
	062	M-S	No
	063	M-S	No
	065	M-S	No
	067	M-S	No
	068	M-S	No
	069	M-S	No
	071	F-NS	No
	072	F-NS	No
	073	F-NS	No
	074	F-NS	No
	075	F-NS	No
	076	F-NS	No
	077	F-NS	No
	078	F-NS	No
	079	F-NS	No
	080	F-NS	No
	081	F-NS	No
	082	F-NS	No
	083	F-NS	No
	084	F-NS	No
	085	F-NS	No
	086	F-NS	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS= Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 41 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.2: Since the last time you were interviewed, have you used any of the following nicotine-containing products? Nicotine Sprays	087	F-NS	No
	088	F-NS	No
	089	F-NS	No
	090	F-NS	No
	091	F-NS	No
	092	F-NS	No
	093	F-NS	No
	094	F-NS	No
	095	F-NS	No
	096	F-NS	No
	097	F-NS	No
	098	F-NS	No
	099	F-NS	No
	100	F-NS	No
	101	F-NS	No
	102	F-NS	No
	103	F-NS	No
	104	M-NS	No
	105	M-NS	No
	106	M-NS	No
	107	M-NS	No
	108	M-NS	No
	109	M-NS	No
	110	M-NS	No
	111	M-NS	No
	112	M-NS	No
	114	M-NS	No
	115	M-NS	No
	116	M-NS	No
	117	M-NS	No
	118	M-NS	No
	119	M-NS	No
	120	M-NS	No
	121	M-NS	No
	122	M-NS	No
	123	M-NS	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629943

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 42 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.2: Since the last time you were interviewed, have you used any of the following nicotine-containing products?			
Nicotine Sprays	124	M-NS	No
	125	M-NS	No
	126	M-NS	No
	127	M-NS	No
	128	M-NS	No
	129	M-NS	No
	130	M-NS	No
	131	M-NS	No
	132	M-NS	No
	133	M-NS	No
	134	M-NS	No
	135	M-NS	No
	500	F-NS	No
	501	F-NS	No
	502	F-S	No
	503	F-S	No
	504	F-S	No
	505	F-NS	No
	506	F-S	No
Other	001	F-S	No
	002	F-S	No
	003	F-S	No
	004	F-S	No
	005	F-S	No
	006	F-S	No
	007	F-S	No
	008	F-S	No
	009	F-S	No
	011	F-S	No
	012	F-S	No
	013	F-S	No
	014	F-S	No
	015	F-S	No
	016	F-S	No
	017	F-S	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629944

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 43 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.2: Since the last time you were interviewed, have you used any of the following nicotine-containing products?			
Other	018	F-S	No
	019	F-S	No
	020	F-S	No
	021	F-S	No
	022	F-S	No
	023	F-S	No
	024	F-S	No
	025	F-S	No
	026	F-S	No
	027	F-S	No
	028	F-S	No
	029	F-S	No
	030	F-S	No
	031	F-S	No
	032	F-S	No
	033	F-S	No
	034	F-S	No
	035	F-S	No
	036	M-S	No
	037	M-S	No
	038	M-S	No
	039	M-S	No
	040	M-S	No
	041	M-S	No
	042	M-S	No
	043	M-S	No
	044	M-S	No
	045	M-S	No
	046	M-S	No
	047	M-S	No
	048	M-S	No
	049	M-S	No
	050	M-S	No
	052	M-S	No
	054	M-S	No
	055	M-S	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 44 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.2: Since the last time you were interviewed, have you used any of the following nicotine-containing products?			
Other	056	M-S	No
	057	M-S	No
	058	M-S	No
	059	M-S	No
	060	M-S	No
	061	M-S	No
	062	M-S	No
	063	M-S	No
	065	M-S	No
	067	M-S	No
	068	M-S	No
	069	M-S	No
	071	F-NS	No
	072	F-NS	No
	073	F-NS	No
	074	F-NS	No
	075	F-NS	No
	076	F-NS	No
	077	F-NS	No
	078	F-NS	No
	079	F-NS	No
	080	F-NS	No
	081	F-NS	No
	082	F-NS	No
	083	F-NS	No
	084	F-NS	No
	085	F-NS	No
	086	F-NS	No
	087	F-NS	No
	088	F-NS	No
	089	F-NS	No
	090	F-NS	No
	091	F-NS	No
	092	F-NS	No
	093	F-NS	No
	094	F-NS	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 45 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.2: Since the last time you were interviewed, have you used any of the following nicotine-containing products?			
Other	095	F-NS	No
	096	F-NS	No
	097	F-NS	No
	098	F-NS	No
	099	F-NS	No
	100	F-NS	No
	101	F-NS	No
	102	F-NS	No
	103	F-NS	No
	104	M-NS	No
	105	M-NS	No
	106	M-NS	No
	107	M-NS	No
	108	M-NS	No
	109	M-NS	No
	110	M-NS	No
	111	M-NS	No
	112	M-NS	No
	114	M-NS	No
	115	M-NS	No
	116	M-NS	No
	117	M-NS	No
	118	M-NS	No
	119	M-NS	No
	120	M-NS	No
	121	M-NS	No
	122	M-NS	No
	123	M-NS	No
	124	M-NS	No
	125	M-NS	No
	126	M-NS	No
	127	M-NS	No
	128	M-NS	No
	129	M-NS	No
	130	M-NS	No
	131	M-NS	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629947

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 46 of 111)

Question	Subject Number	Subject Classification ^a	Response
A.2: Since the last time you were interviewed, have you used any of the following nicotine-containing products?			
Other	132	M-NS	No
	133	M-NS	No
	134	M-NS	No
	135	M-NS	No
	500	F-NS	No
	501	F-NS	No
	502	F-S	No
	503	F-S	No
	504	F-S	No
	505	F-NS	No
	506	F-S	No
I: How did you arrive at this facility?			
	001	F-S	Car, truck, or van
	002	F-S	Car, truck, or van
	003	F-S	Car, truck, or van
	004	F-S	Car, truck, or van
	005	F-S	Car, truck, or van
	006	F-S	Car, truck, or van
	007	F-S	Car, truck, or van
	008	F-S	Car, truck, or van
	009	F-S	Car, truck, or van
	011	F-S	Car, truck, or van
	012	F-S	Car, truck, or van
	013	F-S	Car, truck, or van
	014	F-S	Car, truck, or van
	015	F-S	Car, truck, or van
	016	F-S	Car, truck, or van
	017	F-S	Car, truck, or van
	018	F-S	Car, truck, or van
	019	F-S	Car, truck, or van
	020	F-S	Car, truck, or van
	021	F-S	Car, truck, or van
	022	F-S	Car, truck, or van
	023	F-S	Car, truck, or van
	024	F-S	Car, truck, or van

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 47 of 111)

Question	Subject Number	Subject Classification ^a	Response
1: How did you arrive at this facility?	025	F-S	Car, truck, or van
	026	F-S	Car, truck, or van
	027	F-S	Car, truck, or van
	028	F-S	Car, truck, or van
	029	F-S	Car, truck, or van
	030	F-S	Car, truck, or van
	031	F-S	Car, truck, or van
	032	F-S	Car, truck, or van
	033	F-S	Car, truck, or van
	034	F-S	Car, truck, or van
	035	F-S	Car, truck, or van
	036	M-S	Car, truck, or van
	037	M-S	Car, truck, or van
	038	M-S	Car, truck, or van
	039	M-S	Car, truck, or van
	040	M-S	Car, truck, or van
	041	M-S	Walked the full distance
	042	M-S	Car, truck, or van
	043	M-S	Car, truck, or van
	044	M-S	Car, truck, or van
	045	M-S	Motorcycle
	046	M-S	Car, truck, or van
	047	M-S	Bike
	048	M-S	Car, truck, or van
	049	M-S	Car, truck, or van
	050	M-S	Car, truck, or van
	052	M-S	Car, truck, or van
	054	M-S	Car, truck, or van
	055	M-S	Car, truck, or van
	056	M-S	Car, truck, or van
	057	M-S	Car, truck, or van
	058	M-S	Car, truck, or van
	059	M-S	Car, truck, or van
	060	M-S	Car, truck, or van
	061	M-S	Car, truck, or van
	062	M-S	Car, truck, or van

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 48 of 111)

Question	Subject Number	Subject Classification ^a	Response
1: How did you arrive at this facility?	063	M-S	Car, truck, or van
	065	M-S	Car, truck, or van
	067	M-S	Car, truck, or van
	068	M-S	Car, truck, or van
	069	M-S	Car, truck, or van
	071	F-NS	Car, truck, or van
	072	F-NS	Car, truck, or van
	073	F-NS	Car, truck, or van
	074	F-NS	Car, truck, or van
	075	F-NS	Car, truck, or van
	076	F-NS	Car, truck, or van
	077	F-NS	Car, truck, or van
	078	F-NS	Car, truck, or van
	079	F-NS	Car, truck, or van
	080	F-NS	Car, truck, or van
	081	F-NS	Car, truck, or van
	082	F-NS	Car, truck, or van
	083	F-NS	Car, truck, or van
	084	F-NS	Car, truck, or van
	085	F-NS	Car, truck, or van
	086	F-NS	Car, truck, or van
	087	F-NS	Car, truck, or van
	088	F-NS	Car, truck, or van
	089	F-NS	Car, truck, or van
	090	F-NS	Car, truck, or van
	091	F-NS	Walked the full distance
	092	F-NS	Car, truck, or van
	093	F-NS	Walked the full distance
	094	F-NS	Car, truck, or van
	095	F-NS	Car, truck, or van
	096	F-NS	Car, truck, or van
	097	F-NS	Car, truck, or van
	098	F-NS	Car, truck, or van
	099	F-NS	Car, truck, or van
	100	F-NS	Car, truck, or van
	101	F-NS	Car, truck, or van

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 49 of 111)

Question	Subject Number	Subject Classification ^a	Response
1: How did you arrive at this facility?	102	F-NS	Car, truck, or van
	103	F-NS	Car, truck, or van
	104	M-NS	Walked the full distance
	105	M-NS	Bike
	106	M-NS	Car, truck, or van
	107	M-NS	Car, truck, or van
	108	M-NS	Car, truck, or van
	109	M-NS	Car, truck, or van
	110	M-NS	Car, truck, or van
	111	M-NS	Car, truck, or van
	112	M-NS	Car, truck, or van
	114	M-NS	Car, truck, or van
	115	M-NS	Car, truck, or van
	116	M-NS	Car, truck, or van
	117	M-NS	Car, truck, or van
	118	M-NS	Car, truck, or van
	119	M-NS	Car, truck, or van
	120	M-NS	Car, truck, or van
	121	M-NS	Car, truck, or van
	122	M-NS	Car, truck, or van
	123	M-NS	Car, truck, or van
	124	M-NS	Walked the full distance
	125	M-NS	Car, truck, or van
	126	M-NS	Car, truck, or van
	127	M-NS	Car, truck, or van
	128	M-NS	Walked the full distance
	129	M-NS	Car, truck, or van
	130	M-NS	Car, truck, or van
	131	M-NS	Car, truck, or van
	132	M-NS	Car, truck, or van
	133	M-NS	Car, truck, or van
	134	M-NS	Bike
	135	M-NS	Walked the full distance
	500	F-NS	Car, truck, or van
	501	F-NS	Car, truck, or van
	502	F-S	Car, truck, or van

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 50 of 111)

Question	Subject Number	Subject Classification ^a	Response
1: How did you arrive at this facility?	503	F-S	Car, truck, or van
	504	F-S	Car, truck, or van
	505	F-NS	Car, truck, or van
	506	F-S	Car, truck, or van
2: What was your primary activity in the last 8 to 10 hours?	001	F-S	Sleeping
	002	F-S	Sleeping
	003	F-S	Sleeping
	004	F-S	NON-workday activities
	005	F-S	Sleeping
	006	F-S	Sleeping
	007	F-S	Sleeping
	008	F-S	Sleeping
	009	F-S	Working at your employment
	011	F-S	NON-workday activities
	012	F-S	Sleeping
	013	F-S	Sleeping
	014	F-S	Sleeping
	015	F-S	Sleeping
	016	F-S	Sleeping
	017	F-S	Sleeping
	018	F-S	Working at your employment
	019	F-S	Working at your employment
	020	F-S	NON-workday activities
	021	F-S	NON-workday activities
	022	F-S	Sleeping
	023	F-S	NON-workday activities
	024	F-S	Sleeping
	025	F-S	Sleeping
	026	F-S	Sleeping
	027	F-S	NON-workday activities
	028	F-S	Sleeping
	029	F-S	Sleeping
	030	F-S	Sleeping
	031	F-S	Sleeping

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 51 of 111)

Question	Subject Number	Subject Classification ^a	Response
2: What was your primary activity in the last 8 to 10 hours?	032	F-S	Sleeping
	033	F-S	Sleeping
	034	F-S	Working at your employment
	035	F-S	NON-workday activities
	036	M-S	Working at your employment
	037	M-S	Sleeping
	038	M-S	Sleeping
	039	M-S	Sleeping
	040	M-S	Sleeping
	041	M-S	Sleeping
	042	M-S	Working at your employment
	043	M-S	Sleeping
	044	M-S	Working at your employment
	045	M-S	Sleeping
	046	M-S	Sleeping
	047	M-S	NON-workday activities
	048	M-S	Sleeping
	049	M-S	Sleeping
	050	M-S	Sleeping
	052	M-S	Sleeping
	054	M-S	Working at your employment
	055	M-S	Sleeping
	056	M-S	Sleeping
	057	M-S	Sleeping
	058	M-S	Sleeping
	059	M-S	Sleeping
	060	M-S	Sleeping
	061	M-S	Working at your employment
	062	M-S	NON-workday activities
	063	M-S	Working at your employment
	065	M-S	Sleeping
	067	M-S	Sleeping
	068	M-S	NON-workday activities
	069	M-S	Sleeping
	071	F-NS	Sleeping
	072	F-NS	Sleeping

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629953

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 52 of 111)

Question	Subject Number	Subject Classification ^a	Response
2: What was your primary activity in the last 8 to 10 hours?	073	F-NS	Sleeping
	074	F-NS	Sleeping
	075	F-NS	Sleeping
	076	F-NS	Working at your employment
	077	F-NS	NON-workday activities
	078	F-NS	Sleeping
	079	F-NS	Sleeping
	080	F-NS	Working at your employment
	081	F-NS	NON-workday activities
	082	F-NS	Sleeping
	083	F-NS	Sleeping
	084	F-NS	Sleeping
	085	F-NS	Sleeping
	086	F-NS	Sleeping
	087	F-NS	Sleeping
	088	F-NS	Sleeping
	089	F-NS	Working at your employment
	090	F-NS	Sleeping
	091	F-NS	Sleeping
	092	F-NS	Sleeping
	093	F-NS	Sleeping
	094	F-NS	Sleeping
	095	F-NS	Sleeping
	096	F-NS	NON-workday activities
	097	F-NS	Sleeping
	098	F-NS	Working at your employment
	099	F-NS	Sleeping
	100	F-NS	Sleeping
	101	F-NS	Sleeping
	102	F-NS	Working at your employment
	103	F-NS	Sleeping
	104	M-NS	Sleeping
	105	M-NS	Sleeping
	106	M-NS	Working at your employment
	107	M-NS	Sleeping
	108	M-NS	Sleeping

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 53 of 111)

Question	Subject Number	Subject Classification ^a	Response
2: What was your primary activity in the last 8 to 10 hours?	109	M-NS	NON-workday activities
	110	M-NS	Sleeping
	111	M-NS	Sleeping
	112	M-NS	Sleeping
	114	M-NS	Sleeping
	115	M-NS	Working at your employment
	116	M-NS	Sleeping
	117	M-NS	Sleeping
	118	M-NS	NON-workday activities
	119	M-NS	Sleeping
	120	M-NS	Sleeping
	121	M-NS	Sleeping
	122	M-NS	Sleeping
	123	M-NS	Sleeping
	124	M-NS	Sleeping
	125	M-NS	Sleeping
	126	M-NS	NON-workday activities
	127	M-NS	Working at your employment
	128	M-NS	Working at your employment
	129	M-NS	Working at your employment
	130	M-NS	Sleeping
	131	M-NS	Sleeping
	132	M-NS	Sleeping
	133	M-NS	Sleeping
	134	M-NS	Sleeping
	135	M-NS	Sleeping
	500	F-NS	Sleeping
	501	F-NS	NON-workday activities
	502	F-S	Sleeping
	503	F-S	Sleeping
	504	F-S	Sleeping
	505	F-NS	Sleeping
	506	F-S	NON-workday activities
3: In the past 3 days, have you smoked manufactured cigarettes on a regular basis? That is, have you smoked at least 1 cigarette per day?			
	001	F-S	Yes

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629955

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 54 of 111)

Question	Subject Number	Subject Classification ^a	Response
3: In the past 3 days, have you smoked manufactured cigarettes on a regular basis? That is, have you smoked at least 1 cigarette per day?	002	F-S	Yes
	003	F-S	Yes
	004	F-S	Yes
	005	F-S	Yes
	006	F-S	Yes
	007	F-S	Yes
	008	F-S	Yes
	009	F-S	Yes
	011	F-S	Yes
	012	F-S	Yes
	013	F-S	Yes
	014	F-S	Yes
	015	F-S	Yes
	016	F-S	Yes
	017	F-S	Yes
	018	F-S	Yes
	019	F-S	Yes
	020	F-S	Yes
	021	F-S	Yes
	022	F-S	Yes
	023	F-S	Yes
	024	F-S	Yes
	025	F-S	Yes
	026	F-S	Yes
	027	F-S	Yes
	028	F-S	Yes
	029	F-S	Yes
	030	F-S	Yes
	031	F-S	No
	032	F-S	Yes
	033	F-S	No
	034	F-S	Yes
	035	F-S	Yes
	036	M-S	Yes
	037	M-S	Yes
	038	M-S	Yes

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629956

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 55 of 111)

Question	Subject Number	Subject Classification ^a	Response
3: In the past 3 days, have you smoked manufactured cigarettes on a regular basis? That is, have you smoked at least 1 cigarette per day?	039	M-S	Yes
	040	M-S	Yes
	041	M-S	Yes
	042	M-S	Yes
	043	M-S	Yes
	044	M-S	Yes
	045	M-S	Yes
	046	M-S	Yes
	047	M-S	Yes
	048	M-S	Yes
	049	M-S	Yes
	050	M-S	Yes
	052	M-S	Yes
	055	M-S	Yes
	056	M-S	Yes
	057	M-S	Yes
	058	M-S	Yes
	059	M-S	Yes
	060	M-S	Yes
	061	M-S	Yes
	062	M-S	Yes
	063	M-S	Yes
	065	M-S	No
	067	M-S	Yes
	068	M-S	Yes
	069	M-S	Yes
	502	F-S	Yes
	503	F-S	Yes
	504	F-S	Yes
	506	F-S	Yes
4: Within the past 3 days, on average, how many cigarettes did you smoke per day?	001	F-S	17
	002	F-S	20
	003	F-S	5
	004	F-S	12

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629957

Listing 16.S-14
Weekly Survey by Question: Week 6
(Page 56 of 111)

Question	Subject Number	Subject Classification ^a	Response
4: Within the past 3 days, on average, how many cigarettes did you smoke per day?	005	F-S	4
	006	F-S	20
	007	F-S	20
	008	F-S	20
	009	F-S	12
	011	F-S	25
	012	F-S	22
	013	F-S	20
	014	F-S	17
	015	F-S	2
	016	F-S	20
	017	F-S	25
	018	F-S	10
	019	F-S	4
	020	F-S	30
	021	F-S	5
	022	F-S	20
	023	F-S	7
	024	F-S	12
	025	F-S	20
	026	F-S	20
	027	F-S	12
	028	F-S	20
	029	F-S	15
	030	F-S	20
	032	F-S	10
	034	F-S	13
	035	F-S	20
	036	M-S	18
	037	M-S	16
	038	M-S	20
	039	M-S	40
	040	M-S	6
	041	M-S	12
	042	M-S	19
	043	M-S	24

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 57 of 111)

Question	Subject Number	Subject Classification ^a	Response
4: Within the past 3 days, on average, how many cigarettes did you smoke per day?	044	M-S	10
	045	M-S	8
	046	M-S	20
	047	M-S	7
	048	M-S	10
	049	M-S	16
	050	M-S	3
	052	M-S	13
	055	M-S	20
	056	M-S	2
	057	M-S	20
	058	M-S	10
	059	M-S	22
	060	M-S	15
	061	M-S	CANT ANSWER
	062	M-S	30
	063	M-S	14
	067	M-S	5
	068	M-S	20
	069	M-S	15
	502	F-S	13
	503	F-S	16
	504	F-S	30
	506	F-S	3
5: For the most part, did you smoke your usual brand of cigarettes (your PREFERRED BRAND)?	001	F-S	Yes
	002	F-S	Yes
	003	F-S	Yes
	004	F-S	Yes
	005	F-S	Yes
	006	F-S	Yes
	007	F-S	Yes
	008	F-S	Yes
	009	F-S	Yes
	011	F-S	Yes

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 58 of 111)

Question	Subject Number	Subject Classification ^a	Response
5: For the most part, did you smoke your usual brand of cigarettes (your PREFERRED BRAND)?	012	F-S	Yes
	013	F-S	Yes
	014	F-S	Yes
	015	F-S	Yes
	016	F-S	Yes
	017	F-S	Yes
	018	F-S	Yes
	019	F-S	Yes
	020	F-S	Yes
	021	F-S	Yes
	022	F-S	Yes
	023	F-S	Yes
	024	F-S	Yes
	025	F-S	Yes
	026	F-S	Yes
	027	F-S	Yes
	028	F-S	Yes
	029	F-S	Yes
	030	F-S	Yes
	032	F-S	Yes
	035	F-S	Yes
	036	M-S	Yes
	037	M-S	Yes
	038	M-S	Yes
	039	M-S	Yes
	040	M-S	Yes
	041	M-S	Yes
	042	M-S	Yes
	043	M-S	Yes
	044	M-S	Yes
	045	M-S	Yes
	046	M-S	NO - CAMEL LIGHTS
	047	M-S	Yes
	048	M-S	Yes
	049	M-S	Yes
	050	M-S	Yes

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 59 of 111)

Question	Subject Number	Subject Classification ^a	Response
5: For the most part, did you smoke your usual brand of cigarettes (your PREFERRED BRAND)?	052	M-S	Yes
	056	M-S	Yes
	057	M-S	Yes
	058	M-S	Yes
	059	M-S	Yes
	060	M-S	Yes
	061	M-S	CANT ANSWER
	062	M-S	Yes
	063	M-S	Yes
	067	M-S	Yes
	068	M-S	Yes
	069	M-S	Yes
	502	F-S	Yes
	503	F-S	Yes
	504	F-S	Yes
	506	F-S	Yes
6: Indicate any changes in the way that you smoked since your last interview. (Select all that apply.)			
Changed brands	055	M-S	X
	061	M-S	X
Reduced the number of cigarettes smoked	021	F-S	X
	023	F-S	X
	024	F-S	X
	027	F-S	X
	038	M-S	X
	045	M-S	X
Increased the number of cigarettes smoked	025	F-S	X
	035	F-S	X
No change	001	F-S	X
	002	F-S	X
	003	F-S	X
	004	F-S	X
	005	F-S	X

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 60 of 111)

Question	Subject Number	Subject Classification ^a	Response
6: Indicate any changes in the way that you smoked since your last interview. (Select all that apply.) No change	006	F-S	X
	007	F-S	X
	008	F-S	X
	009	F-S	X
	011	F-S	X
	012	F-S	X
	013	F-S	X
	014	F-S	X
	015	F-S	X
	016	F-S	X
	017	F-S	X
	018	F-S	X
	019	F-S	X
	020	F-S	X
	022	F-S	X
	026	F-S	X
	028	F-S	X
	029	F-S	X
	030	F-S	X
	032	F-S	X
	034	F-S	X
	036	M-S	X
	037	M-S	X
	039	M-S	X
	040	M-S	X
	041	M-S	X
	042	M-S	X
	043	M-S	X
	044	M-S	X
	046	M-S	X
	047	M-S	X
	048	M-S	X
	049	M-S	X
	050	M-S	X
	052	M-S	X
	056	M-S	X

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629962

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 61 of 111)

Question	Subject Number	Subject Classification ^a	Response
6: Indicate any changes in the way that you smoked since your last interview. (Select all that apply.) No change	057	M-S	X
	058	M-S	X
	059	M-S	X
	060	M-S	X
	062	M-S	X
	063	M-S	X
	067	M-S	X
	068	M-S	X
	069	M-S	X
	502	F-S	X
	503	F-S	X
	504	F-S	X
	506	F-S	X
7: In the past 3 days did you smoke other brands than your PREFERRED BRAND?	001	F-S	No
	002	F-S	No
	003	F-S	No
	004	F-S	No
	005	F-S	No
	006	F-S	No
	007	F-S	No
	008	F-S	No
	009	F-S	No
	011	F-S	No
	012	F-S	No
	013	F-S	No
	014	F-S	No
	015	F-S	No
	016	F-S	No
	017	F-S	No
	018	F-S	No
	019	F-S	No
	020	F-S	No
	021	F-S	No
	022	F-S	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 62 of 111)

Question	Subject Number	Subject Classification ^a	Response
7: In the past 3 days did you smoke other brands than your PREFERRED BRAND?	023	F-S	No
	024	F-S	No
	025	F-S	No
	026	F-S	No
	027	F-S	No
	028	F-S	No
	029	F-S	No
	030	F-S	No
	032	F-S	No
	034	F-S	Yes
	035	F-S	No
	036	M-S	No
	037	M-S	No
	038	M-S	No
	039	M-S	No
	040	M-S	No
	041	M-S	No
	042	M-S	No
	043	M-S	No
	044	M-S	No
	045	M-S	No
	046	M-S	Yes
	047	M-S	No
	048	M-S	No
	049	M-S	No
	050	M-S	No
	052	M-S	No
	055	M-S	Yes
	056	M-S	No
	057	M-S	No
	058	M-S	No
	059	M-S	No
	060	M-S	No
	061	M-S	CANT ANSWER
	062	M-S	No
	063	M-S	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629964

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 63 of 111)

Question	Subject Number	Subject Classification ^a	Response
7: In the past 3 days did you smoke other brands than your PREFERRED BRAND?	067	M-S	No
	068	M-S	No
	069	M-S	No
	502	F-S	No
	503	F-S	No
	504	F-S	No
	506	F-S	No
8: How many different brands did you smoke other than your PREFERRED BRAND in the last 3 days?	034	F-S	1
	046	M-S	1
	055	M-S	1
	061	M-S	CAN'T ANSWER
9: What is the full name this alternate brand of cigarettes you smoked in the last 3 days? (Referred to as "ALTERNATE BRAND" for the following questions.) For Brand Number 1	034	F-S	MARLBORO ULTRA LIGHTS
	046	M-S	CAMEL LIGHTS
	055	M-S	BASIC ULTRA LIGHTS
	061	M-S	CAN'T ANSWER
10: Is this ALTERNATE BRAND (from Question 9) full flavor, milds, lights, or ultra lights? For Brand Number 1	034	F-S	Ultra lights
	046	M-S	Lights
	055	M-S	Ultra lights
	061	M-S	CAN'T ANSWER
11: Is this ALTERNATE BRAND (from Question 9) menthol or non-menthol? For Brand Number 1	034	F-S	Non-menthol (regular)
	046	M-S	Non-menthol (regular)
	055	M-S	Non-menthol (regular)
	061	M-S	CAN'T ANSWER
12: Is the length of this ALTERNATE BRAND (from Question 9) king size or shorter, 100s, or 120s? For Brand Number 1	034	F-S	King size or shorter

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 64 of 111)

Question	Subject Number	Subject Classification ^a	Response
12: Is the length of this ALTERNATE BRAND (from Question 9) king size or shorter, 100s, or 120s? For Brand Number 1	046 055 061	M-S M-S M-S	King size or shorter King size or shorter CANT ANSWER
13: Is this ALTERNATE BRAND (from Question 9) usually soft pack or box? For Brand Number 1	034 046 055 061	F-S M-S M-S M-S	Box Box Soft pack CANT ANSWER
14: Is this ALTERNATE BRAND (from Question 9) filtered or non-filtered? For Brand Number 1	034 046 055 061	F-S M-S M-S M-S	Filtered Filtered Filtered CANT ANSWER
15: How many of the ALTERNATE BRAND (from Question 9) did you smoke in the last 3 days? For Brand Number 1	034 046 055 061	F-S M-S M-S M-S	39 57 1 CANT ANSWER
16: Within the last 3 days, did you work indoors or in an enclosed space where you were exposed to tobacco smoke of others?	001 002 003 004 005 006 007 008 009	F-S F-S F-S F-S F-S F-S F-S F-S F-S	No No No No No No No No No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 65 of 111)

Question	Subject Number	Subject Classification ^a	Response
16: Within the last 3 days, did you work indoors or in an enclosed space where you were exposed to tobacco smoke of others?	011	F-S	No
	012	F-S	No
	013	F-S	No
	014	F-S	No
	015	F-S	No
	016	F-S	No
	017	F-S	No
	018	F-S	No
	019	F-S	Yes
	020	F-S	No
	021	F-S	No
	022	F-S	No
	023	F-S	Yes
	024	F-S	No
	025	F-S	No
	026	F-S	No
	027	F-S	No
	028	F-S	No
	029	F-S	No
	030	F-S	No
	031	F-S	No
	032	F-S	No
	033	F-S	No
	034	F-S	No
	035	F-S	Yes
	036	M-S	No
	037	M-S	Yes
	038	M-S	No
	039	M-S	No
	040	M-S	No
	041	M-S	No
	042	M-S	No
	043	M-S	No
	044	M-S	No
	045	M-S	No
	046	M-S	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629967

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 66 of 111)

Question	Subject Number	Subject Classification ^a	Response
16: Within the last 3 days, did you work indoors or in an enclosed space where you were exposed to tobacco smoke of others?	047	M-S	No
	048	M-S	No
	049	M-S	No
	050	M-S	No
	052	M-S	No
	054	M-S	No
	055	M-S	No
	056	M-S	No
	057	M-S	No
	058	M-S	No
	059	M-S	No
	060	M-S	No
	061	M-S	No
	062	M-S	No
	063	M-S	No
	065	M-S	No
	067	M-S	No
	068	M-S	No
	069	M-S	No
	071	F-NS	No
	072	F-NS	No
	073	F-NS	No
	074	F-NS	No
	075	F-NS	No
	076	F-NS	No
	077	F-NS	No
	078	F-NS	No
	079	F-NS	No
	080	F-NS	No
	081	F-NS	No
	082	F-NS	No
	083	F-NS	No
	084	F-NS	No
	085	F-NS	No
	086	F-NS	No
	087	F-NS	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629968

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 67 of 111)

Question	Subject Number	Subject Classification ^a	Response
16: Within the last 3 days, did you work indoors or in an enclosed space where you were exposed to tobacco smoke of others?	088	F-NS	No
	089	F-NS	No
	090	F-NS	No
	091	F-NS	No
	092	F-NS	No
	093	F-NS	No
	094	F-NS	No
	095	F-NS	No
	096	F-NS	No
	097	F-NS	No
	098	F-NS	No
	099	F-NS	No
	100	F-NS	No
	101	F-NS	No
	102	F-NS	No
	103	F-NS	No
	104	M-NS	No
	105	M-NS	No
	106	M-NS	No
	107	M-NS	Yes
	108	M-NS	No
	109	M-NS	No
	110	M-NS	Yes
	111	M-NS	No
	112	M-NS	No
	114	M-NS	No
	115	M-NS	No
	116	M-NS	No
	117	M-NS	No
	118	M-NS	No
	119	M-NS	No
	120	M-NS	No
	121	M-NS	No
	122	M-NS	No
	123	M-NS	No
	124	M-NS	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 68 of 111)

Question	Subject Number	Subject Classification ^a	Response
16: Within the last 3 days, did you work indoors or in an enclosed space where you were exposed to tobacco smoke of others?	125	M-NS	No
	126	M-NS	No
	127	M-NS	No
	128	M-NS	No
	129	M-NS	No
	130	M-NS	No
	131	M-NS	No
	132	M-NS	No
	133	M-NS	No
	134	M-NS	No
	135	M-NS	No
	500	F-NS	Yes
	501	F-NS	No
	502	F-S	No
	503	F-S	No
	504	F-S	No
	505	F-NS	No
	506	F-S	No
17: Over the past 3 days, how many jobs have you worked at in which you were exposed to the tobacco smoke of other smokers indoors or in an enclosed space on a regular basis?	019	F-S	1
	023	F-S	1
	035	F-S	1
	037	M-S	1
	107	M-NS	1
	110	M-NS	1
	500	F-NS	1
18: During which of the last 3 days were you exposed to tobacco smoke from others at this workplace indoors or in an enclosed space?			
For Job Number 1			
Day 1	019	F-S	No
	023	F-S	Yes
	035	F-S	No
	037	M-S	Yes
	107	M-NS	Yes
	110	M-NS	Yes

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 69 of 111)

Question	Subject Number	Subject Classification ^a	Response
18: During which of the last 3 days were you exposed to tobacco smoke from others at this workplace indoors or in an enclosed space?			
For Job Number 1			
Day 1	500	F-NS	No
Day 2	019	F-S	Yes
	023	F-S	Yes
	035	F-S	No
	037	M-S	Yes
	107	M-NS	Yes
	110	M-NS	Yes
	500	F-NS	No
Day 3	019	F-S	Yes
	023	F-S	No
	035	F-S	Yes
	037	M-S	No
	107	M-NS	No
	110	M-NS	Yes
	500	F-NS	Yes
19: For how long each day on average during the last 3 days were you regularly exposed to tobacco smoke at this workplace indoors or in an enclosed space?			
For Job Number 1			
	019	F-S	1/2
	023	F-S	7
	035	F-S	4
	037	M-S	2 1/2
	107	M-NS	8
	110	M-NS	6
	500	F-NS	5
20: Would you say that the amount of tobacco smoke to which you were exposed in this workplace indoors or in an enclosed space was usually light, moderate, or heavy in the last 3 days?			
For Job Number 1			
	019	F-S	Moderate
	023	F-S	Moderate
	035	F-S	Moderate
	037	M-S	Light
	107	M-NS	Heavy

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629971

Question	Subject Number	Subject Classification ¹	Response
20: Would you say that the amount of tobacco smoke to which you were exposed in this workplace indoors or in an enclosed space was usually light, moderate, or heavy in the last 3 days?			
For Job Number 1	110	M-NS	Moderate
	500	F-NS	Light
21: Do you live with someone in a marital type relationship?			
	001	F-S	Yes
	002	F-S	No
	003	F-S	No
	004	F-S	Yes
	005	F-S	Yes
	006	F-S	No
	007	F-S	No
	008	F-S	Yes
	009	F-S	No
	011	F-S	No
	012	F-S	Yes
	013	F-S	No
	014	F-S	Yes
	015	F-S	Yes
	016	F-S	Yes
	017	F-S	No
	018	F-S	Yes
	019	F-S	Yes
	020	F-S	Yes
	021	F-S	No
	022	F-S	No
	023	F-S	Yes
	024	F-S	Yes
	025	F-S	No
	026	F-S	No
	027	F-S	Yes
	028	F-S	No
	029	F-S	No
	030	F-S	Yes
	031	F-S	No
	032	F-S	Yes

PM13006629972

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 71 of 111)

Question	Subject Number	Subject Classification ^a	Response
21: Do you live with someone in a marital type relationship?	033	F-S	Yes
	034	F-S	No
	035	F-S	No
	036	M-S	Yes
	037	M-S	Yes
	038	M-S	Yes
	039	M-S	Yes
	040	M-S	Yes
	041	M-S	No
	042	M-S	No
	043	M-S	Yes
	044	M-S	No
	045	M-S	No
	046	M-S	Yes
	047	M-S	No
	048	M-S	Yes
	049	M-S	Yes
	050	M-S	Yes
	052	M-S	Yes
	054	M-S	Yes
	055	M-S	No
	056	M-S	No
	057	M-S	No
	058	M-S	Yes
	059	M-S	Yes
	060	M-S	No
	061	M-S	No
	062	M-S	No
	063	M-S	Yes
	065	M-S	No
	067	M-S	No
	068	M-S	No
	069	M-S	No
	071	F-NS	Yes
	072	F-NS	Yes
	073	F-NS	Yes

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629973

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 72 of 111)

Question	Subject Number	Subject Classification ^a	Response
21: Do you live with someone in a marital type relationship?	074	F-NS	No
	075	F-NS	No
	076	F-NS	No
	077	F-NS	Yes
	078	F-NS	Yes
	079	F-NS	No
	080	F-NS	No
	081	F-NS	Yes
	082	F-NS	No
	083	F-NS	Yes
	084	F-NS	No
	085	F-NS	Yes
	086	F-NS	Yes
	087	F-NS	Yes
	088	F-NS	Yes
	089	F-NS	Yes
	090	F-NS	Yes
	091	F-NS	No
	092	F-NS	Yes
	093	F-NS	No
	094	F-NS	Yes
	095	F-NS	Yes
	096	F-NS	Yes
	097	F-NS	Yes
	098	F-NS	No
	099	F-NS	Yes
	100	F-NS	No
	101	F-NS	Yes
	102	F-NS	Yes
	103	F-NS	No
	104	M-NS	No
	105	M-NS	No
	106	M-NS	No
	107	M-NS	No
	108	M-NS	No
	109	M-NS	Yes

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629974

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 73 of 111)

Question	Subject Number	Subject Classification ^a	Response
21: Do you live with someone in a marital type relationship?	110	M-NS	Yes
	111	M-NS	Yes
	112	M-NS	Yes
	114	M-NS	No
	115	M-NS	Yes
	116	M-NS	No
	117	M-NS	No
	118	M-NS	Yes
	119	M-NS	Yes
	120	M-NS	Yes
	121	M-NS	No
	122	M-NS	No
	123	M-NS	Yes
	124	M-NS	No
	125	M-NS	Yes
	126	M-NS	Yes
	127	M-NS	Yes
	128	M-NS	Yes
	129	M-NS	Yes
	130	M-NS	Yes
	131	M-NS	No
	132	M-NS	No
	133	M-NS	Yes
	134	M-NS	No
	135	M-NS	No
	500	F-NS	No
	501	F-NS	Yes
	502	F-S	Yes
	503	F-S	Yes
	504	F-S	Yes
	505	F-NS	Yes
	506	F-S	Yes
22: At home, did your spouse/partner smoke in your presence during the past 3 days?	001	F-S	No
	004	F-S	Yes

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 74 of 111)

Question	Subject Number	Subject Classification ¹	Response
22: At home, did your spouse/partner smoke in your presence during the past 3 days?	005	F-S	Yes
	008	F-S	No
	012	F-S	Yes
	014	F-S	No
	015	F-S	No
	016	F-S	No
	018	F-S	No
	019	F-S	No
	020	F-S	No
	023	F-S	No
	024	F-S	No
	027	F-S	No
	030	F-S	Yes
	032	F-S	Yes
	033	F-S	No
	036	M-S	No
	037	M-S	Yes
	038	M-S	No
	039	M-S	No
	040	M-S	No
	043	M-S	Yes
	046	M-S	No
	048	M-S	No
	049	M-S	No
	050	M-S	No
	052	M-S	Yes
	054	M-S	No
	058	M-S	Yes
	059	M-S	Yes
	063	M-S	No
	071	F-NS	No
	072	F-NS	No
	073	F-NS	No
	077	F-NS	No
	078	F-NS	No
	081	F-NS	No

¹ Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629976

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 75 of 111)

Question	Subject Number	Subject Classification ^a	Response
22: At home, did your spouse/partner smoke in your presence during the past 3 days?	083	F-NS	No
	085	F-NS	No
	086	F-NS	No
	087	F-NS	No
	088	F-NS	No
	089	F-NS	No
	090	F-NS	No
	092	F-NS	No
	094	F-NS	No
	095	F-NS	No
	096	F-NS	No
	097	F-NS	No
	099	F-NS	No
	101	F-NS	No
	102	F-NS	No
	109	M-NS	No
	110	M-NS	Yes
	111	M-NS	No
	112	M-NS	No
	115	M-NS	No
	118	M-NS	No
	119	M-NS	No
	120	M-NS	No
	123	M-NS	No
	125	M-NS	No
	126	M-NS	No
	127	M-NS	No
	128	M-NS	Yes
	129	M-NS	No
	130	M-NS	No
	133	M-NS	No
	501	F-NS	No
	502	F-S	Yes
	503	F-S	No
	504	F-S	Yes
	505	F-NS	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629977

Draft 1: 24 July 2002

Page 14622 of 15132

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 76 of 111)

Question	Subject Number	Subject Classification ^a	Response
22: At home, did your spouse/partner smoke in your presence during the past 3 days?	506	F-S	No
23: What did your spouse/partner smoke in your presence in the last 3 days?	004	F-S	Manufactured Cigarettes
	005	F-S	Manufactured Cigarettes
	012	F-S	Cigars
	030	F-S	Manufactured Cigarettes
	032	F-S	Manufactured Cigarettes
	037	M-S	Manufactured Cigarettes
	043	M-S	Manufactured Cigarettes
	052	M-S	Manufactured Cigarettes
	058	M-S	Manufactured Cigarettes
	059	M-S	Manufactured Cigarettes
	110	M-NS	Manufactured Cigarettes
	128	M-NS	Manufactured Cigarettes
	502	F-S	Manufactured Cigarettes
	504	F-S	Manufactured Cigarettes
24: During the last 3 days, how often did your spouse/partner smoke PRODUCT (from Question 23) at home when you were together?	004	F-S	Every day (all 3 days)
	005	F-S	Every day (all 3 days)
	012	F-S	Every day (all 3 days)
	030	F-S	Every day (all 3 days)
	032	F-S	2 days
	037	M-S	Every day (all 3 days)
	043	M-S	1 day
	052	M-S	2 days
	058	M-S	Every day (all 3 days)
	059	M-S	Every day (all 3 days)
	110	M-NS	Every day (all 3 days)
	128	M-NS	Every day (all 3 days)
	502	F-S	Every day (all 3 days)
	504	F-S	Every day (all 3 days)
25: In the last 3 days, on average how many PRODUCT (from Question 23) did your spouse/partner smoke per day at home when you were together?	004	F-S	15

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 77 of 111)

Question	Subject Number	Subject Classification ^a	Response
25: In the last 3 days, on average how many PRODUCT (from Question 23) did your spouse/partner smoke per day at home when you were together?	005	F-S	6
	012	F-S	3
	030	F-S	4
	032	F-S	3
	037	M-S	5
	043	M-S	10
	052	M-S	1
	058	M-S	20
	059	M-S	13
	110	M-NS	25
	128	M-NS	2
	502	F-S	10
	504	F-S	15
26: During the last 3 days, for how long each day on average were you exposed to your spouse/partner's tobacco smoke from PRODUCT (from Question 23) at home when you were together?	004	F-S	16
	005	F-S	5
	012	F-S	2
	030	F-S	4
	032	F-S	3
	037	M-S	3
	043	M-S	6
	052	M-S	1/2
	058	M-S	15
	059	M-S	5
	110	M-NS	4
	128	M-NS	1/2
	502	F-S	4
	504	F-S	6
27: Over the past 3 days, have there been any changes in the amount your spouse/partner smoked PRODUCT (from Question 23) in your presence at home when you were together?	004	F-S	No
	005	F-S	No
	012	F-S	No
	030	F-S	No
	032	F-S	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 78 of 111)

Question	Subject Number	Subject Classification ^a	Response
27: Over the past 3 days, have there been any changes in the amount your spouse/partner smoked PRODUCT (from Question 23) in your presence at home when you were together?	037	M-S	No
	043	M-S	No
	052	M-S	No
	058	M-S	No
	059	M-S	No
	110	M-NS	No
	128	M-NS	No
	502	F-S	No
30: Within the last 3 days, were you exposed to tobacco smoke from persons other than a spouse/partner who lived in the same residence or who visited regularly?	504	F-S	No
	001	F-S	No
	002	F-S	Yes
	003	F-S	Yes
	004	F-S	No
	005	F-S	No
	006	F-S	No
	007	F-S	No
	008	F-S	No
	009	F-S	No
	011	F-S	No
	012	F-S	No
	013	F-S	No
	014	F-S	No
	015	F-S	No
	016	F-S	No
	017	F-S	No
	018	F-S	No
	019	F-S	No
	020	F-S	No
	021	F-S	No
	022	F-S	No
	023	F-S	No
	024	F-S	No
	025	F-S	No
	026	F-S	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 79 of 111)

Question	Subject Number	Subject Classification ^a	Response
30: Within the last 3 days, were you exposed to tobacco smoke from persons other than a spouse/partner who lived in the same residence or who visited regularly?	027	F-S	No
	028	F-S	Yes
	029	F-S	Yes
	030	F-S	No
	031	F-S	No
	032	F-S	No
	033	F-S	No
	034	F-S	No
	035	F-S	Yes
	036	M-S	No
	037	M-S	No
	038	M-S	No
	039	M-S	No
	040	M-S	Yes
	041	M-S	No
	042	M-S	No
	043	M-S	No
	044	M-S	No
	045	M-S	Yes
	046	M-S	No
	047	M-S	No
	048	M-S	Yes
	049	M-S	No
	050	M-S	No
	052	M-S	No
	054	M-S	No
	055	M-S	No
	056	M-S	No
	057	M-S	No
	058	M-S	No
	059	M-S	No
	060	M-S	Yes
	061	M-S	No
	062	M-S	No
	063	M-S	No
	065	M-S	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629981

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 80 of 111)

Question	Subject Number	Subject Classification ^a	Response
30: Within the last 3 days, were you exposed to tobacco smoke from persons other than a spouse/partner who lived in the same residence or who visited regularly?	067	M-S	No
	068	M-S	No
	069	M-S	No
	071	F-NS	No
	072	F-NS	No
	073	F-NS	No
	074	F-NS	No
	075	F-NS	No
	076	F-NS	No
	077	F-NS	No
	078	F-NS	No
	079	F-NS	No
	080	F-NS	No
	081	F-NS	No
	082	F-NS	No
	083	F-NS	No
	084	F-NS	No
	085	F-NS	No
	086	F-NS	No
	087	F-NS	No
	088	F-NS	No
	089	F-NS	No
	090	F-NS	No
	091	F-NS	No
	092	F-NS	No
	093	F-NS	No
	094	F-NS	No
	095	F-NS	No
	096	F-NS	No
	097	F-NS	No
	098	F-NS	No
	099	F-NS	No
	100	F-NS	No
	101	F-NS	No
	102	F-NS	No
	103	F-NS	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629982

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 81 of 111)

Question	Subject Number	Subject Classification ^a	Response
30: Within the last 3 days, were you exposed to tobacco smoke from persons other than a spouse/partner who lived in the same residence or who visited regularly?	104	M-NS	Yes
	105	M-NS	No
	106	M-NS	No
	107	M-NS	No
	108	M-NS	No
	109	M-NS	No
	110	M-NS	No
	111	M-NS	No
	112	M-NS	No
	114	M-NS	No
	115	M-NS	No
	116	M-NS	No
	117	M-NS	No
	118	M-NS	No
	119	M-NS	No
	120	M-NS	No
	121	M-NS	No
	122	M-NS	No
	123	M-NS	No
	124	M-NS	No
	125	M-NS	No
	126	M-NS	No
	127	M-NS	No
	128	M-NS	No
	129	M-NS	No
	130	M-NS	No
	131	M-NS	No
	132	M-NS	No
	133	M-NS	No
	134	M-NS	No
	135	M-NS	No
	500	F-NS	No
	501	F-NS	No
	502	F-S	No
	503	F-S	No
	504	F-S	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 82 of 111)

Question	Subject Number	Subject Classification ^a	Response
30: Within the last 3 days, were you exposed to tobacco smoke from persons other than a spouse/partner who lived in the same residence or who visited regularly?	505	F-NS	No
	506	F-S	No
31: How many different people, not including a spouse/partner, exposed you to tobacco smoke in your home during the last 3 days?	002	F-S	1
	003	F-S	1
	028	F-S	1
	029	F-S	1
	035	F-S	1
	040	M-S	1
	045	M-S	1
	048	M-S	1
	060	M-S	1
	104	M-NS	2
32: On which of the last 3 days were you exposed to the tobacco smoke of this person at your home? Think of Day 1 as the beginning of the 3 days and Day 3 as yesterday.			
For Person Number 1			
Day 1	002	F-S	Yes
	003	F-S	No
	028	F-S	No
	029	F-S	Yes
	035	F-S	No
	040	M-S	No
	045	M-S	Yes
	048	M-S	Yes
	060	M-S	Yes
	104	M-NS	No
Day 2	002	F-S	Yes
	003	F-S	No
	028	F-S	Yes
	029	F-S	Yes
	035	F-S	No
	040	M-S	No
	045	M-S	Yes
	048	M-S	Yes

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 83 of 111)

Question	Subject Number	Subject Classification ^a	Response
32: On which of the last 3 days were you exposed to the tobacco smoke of this person at your home? Think of Day 1 as the beginning of the 3 days and Day 3 as yesterday.			
For Person Number 1			
Day 2	060	M-S	Yes
	104	M-NS	No
Day 3	002	F-S	Yes
	003	F-S	Yes
	028	F-S	Yes
	029	F-S	Yes
	035	F-S	Yes
	040	M-S	Yes
	045	M-S	Yes
	048	M-S	Yes
	060	M-S	Yes
	104	M-NS	Yes
For Person Number 2			
Day 1	104	M-NS	No
Day 2	104	M-NS	Yes
Day 3	104	M-NS	No
33: What did this person smoke in your presence in the last 3 days?			
For Person Number 1			
	002	F-S	Manufactured Cigarettes
	003	F-S	Manufactured Cigarettes
	028	F-S	Manufactured Cigarettes
	029	F-S	Manufactured Cigarettes
	035	F-S	Manufactured Cigarettes
	040	M-S	Manufactured Cigarettes
	045	M-S	Manufactured Cigarettes
	048	M-S	Manufactured Cigarettes
	060	M-S	Manufactured Cigarettes
	104	M-NS	Manufactured Cigarettes
For Person Number 2			
	104	M-NS	Manufactured Cigarettes
34: In the last 3 days, how often did this person smoke PRODUCT (from Question 33) in your home when you were together?			
For Person Number 1			
	002	F-S	EVERYDAY

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629985

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 84 of 111)

Question	Subject Number	Subject Classification ^a	Response
34: In the last 3 days, how often did this person smoke PRODUCT (from Question 33) in your home when you were together?			
For Person Number 1			
	003	F-S	1 day
	028	F-S	2 days
	029	F-S	EVERYDAY
	035	F-S	1 day
	040	M-S	1 day
	045	M-S	EVERYDAY
	048	M-S	EVERYDAY
	060	M-S	EVERYDAY
For Person Number 2			
	104	M-NS	1 day
	104	M-NS	1 day
35: On a typical day during the last 3 days, on average how many PRODUCT (from Question 33) did this person smoke in your home when you were together?			
For Person Number 1			
	002	F-S	8
	003	F-S	4
	028	F-S	10
	029	F-S	10
	035	F-S	5
	040	M-S	10
	045	M-S	4
	048	M-S	5
	060	M-S	10
For Person Number 2			
	104	M-NS	1
	104	M-NS	1
36: During the last 3 days, for how long each day on average were you exposed to this person's tobacco smoke from PRODUCT (from Question 33) at your home when you were together?			
For Person Number 1			
	002	F-S	4
	003	F-S	4
	028	F-S	3
	029	F-S	4
	035	F-S	5
	040	M-S	1

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 85 of 111)

Question	Subject Number	Subject Classification ^a	Response
36: During the last 3 days, for how long each day on average were you exposed to this person's tobacco smoke from PRODUCT (from Question 33) at your home when you were together?			
For Person Number 1	045	M-S	2
	048	M-S	2 1/2
	060	M-S	4
	104	M-NS	1/2
For Person Number 2	104	M-NS	1/2
37: Within the last 3 days, have you traveled in an enclosed vehicle that was smoky or where you could at least smell tobacco smoke of others most of the time?			
	001	F-S	No
	002	F-S	Yes
	003	F-S	No
	004	F-S	Yes
	005	F-S	Yes
	006	F-S	No
	007	F-S	No
	008	F-S	No
	009	F-S	No
	011	F-S	No
	012	F-S	Yes
	013	F-S	No
	014	F-S	No
	015	F-S	No
	016	F-S	No
	017	F-S	No
	018	F-S	No
	019	F-S	No
	020	F-S	No
	021	F-S	Yes
	022	F-S	No
	023	F-S	Yes
	024	F-S	No
	025	F-S	Yes
	026	F-S	Yes
	027	F-S	No
	028	F-S	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 86 of 111)

Question	Subject Number	Subject Classification ^a	Response
37: Within the last 3 days, have you traveled in an enclosed vehicle that was smoky or where you could at least smell tobacco smoke of others most of the time?	029	F-S	Yes
	030	F-S	Yes
	031	F-S	No
	032	F-S	Yes
	033	F-S	No
	034	F-S	No
	035	F-S	No
	036	M-S	No
	037	M-S	No
	038	M-S	Yes
	039	M-S	No
	040	M-S	Yes
	041	M-S	No
	042	M-S	No
	043	M-S	No
	044	M-S	No
	045	M-S	No
	046	M-S	No
	047	M-S	No
	048	M-S	Yes
	049	M-S	No
	050	M-S	No
	052	M-S	No
	054	M-S	No
	055	M-S	No
	056	M-S	No
	057	M-S	No
	058	M-S	Yes
	059	M-S	No
	060	M-S	No
	061	M-S	No
	062	M-S	No
	063	M-S	No
	065	M-S	No
	067	M-S	No
	068	M-S	Yes

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629988

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 87 of 111)

Question	Subject Number	Subject Classification ^a	Response
37: Within the last 3 days, have you traveled in an enclosed vehicle that was smoky or where you could at least smell tobacco smoke of others most of the time?	069	M-S	No
	071	F-NS	No
	072	F-NS	No
	073	F-NS	No
	074	F-NS	No
	075	F-NS	No
	076	F-NS	No
	077	F-NS	No
	078	F-NS	No
	079	F-NS	No
	080	F-NS	Yes
	081	F-NS	No
	082	F-NS	No
	083	F-NS	No
	084	F-NS	No
	085	F-NS	No
	086	F-NS	No
	087	F-NS	No
	088	F-NS	No
	089	F-NS	No
	090	F-NS	No
	091	F-NS	No
	092	F-NS	No
	093	F-NS	No
	094	F-NS	No
	095	F-NS	No
	096	F-NS	No
	097	F-NS	No
	098	F-NS	No
	099	F-NS	No
	100	F-NS	No
	101	F-NS	No
	102	F-NS	No
	103	F-NS	No
	104	M-NS	No
	105	M-NS	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629989

Draft 1: 24 July 2002

Page 14634 of 15132

Listing 16.5-14
Weekly Survey by Question, Week 6
(Page 88 of 111)

Question	Subject Number	Subject Classification ^a	Response
37: Within the last 3 days, have you traveled in an enclosed vehicle that was smoky or where you could at least smell tobacco smoke of others most of the time?	106	M-NS	No
	107	M-NS	No
	108	M-NS	No
	109	M-NS	No
	110	M-NS	Yes
	111	M-NS	No
	112	M-NS	No
	114	M-NS	No
	115	M-NS	No
	116	M-NS	No
	117	M-NS	No
	118	M-NS	No
	119	M-NS	No
	120	M-NS	No
	121	M-NS	No
	122	M-NS	No
	123	M-NS	No
	124	M-NS	No
	125	M-NS	No
	126	M-NS	No
	127	M-NS	No
	128	M-NS	No
	129	M-NS	No
	130	M-NS	No
	131	M-NS	No
	132	M-NS	No
	133	M-NS	No
	134	M-NS	No
	135	M-NS	Yes
	500	F-NS	No
	501	F-NS	No
	502	F-S	Yes
	503	F-S	No
	504	F-S	Yes
	505	F-NS	No
	506	F-S	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 89 of 111)

Question	Subject Number	Subject Classification ^a	Response
38: How many different vehicles did you travel in during the last 3 days which were smoky or where you could at least smell tobacco smoke of others most of the time?	002	F-S	2
	004	F-S	1
	005	F-S	1
	012	F-S	1
	021	F-S	1
	023	F-S	1
	025	F-S	1
	026	F-S	1
	029	F-S	1
	030	F-S	1
	032	F-S	1
	038	M-S	1
	040	M-S	1
	048	M-S	1
	058	M-S	1
	068	M-S	1
	080	F-NS	1
	110	M-NS	1
	135	M-NS	1
	502	F-S	1
	504	F-S	1
39: What type of vehicle was this? For Vehicle Number 1	002	F-S	Car, truck, or van
	004	F-S	Car, truck, or van
	005	F-S	Car, truck, or van
	012	F-S	Car, truck, or van
	021	F-S	Car, truck, or van
	023	F-S	Car, truck, or van
	025	F-S	Car, truck, or van
	026	F-S	Car, truck, or van
	029	F-S	Car, truck, or van
	030	F-S	Car, truck, or van
	032	F-S	Car, truck, or van
	038	M-S	Car, truck, or van

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 90 of 111)

Question	Subject Number	Subject Classification ^a	Response
39: What type of vehicle was this? For Vehicle Number 1	040	M-S	Car, truck, or van
	048	M-S	Car, truck, or van
	058	M-S	Car, truck, or van
	068	M-S	Car, truck, or van
	080	F-NS	Car, truck, or van
	110	M-NS	Car, truck, or van
	135	M-NS	Car, truck, or van
	502	F-S	Car, truck, or van
	504	F-S	Car, truck, or van
For Vehicle Number 2	002	F-S	Car, truck, or van
40: On which of the last 3 days were you exposed to the tobacco smoke in this VEHICLE (from Question 39)? Think of Day 1 as the beginning of the 3 days and Day 3 as yesterday. For Vehicle Number 1 Day 1	002	F-S	Yes
	004	F-S	Yes
	005	F-S	Yes
	012	F-S	Yes
	021	F-S	Yes
	023	F-S	Yes
	025	F-S	No
	026	F-S	No
	029	F-S	No
	030	F-S	Yes
	032	F-S	No
	038	M-S	Yes
	040	M-S	No
	048	M-S	Yes
	058	M-S	No
	068	M-S	No
	080	F-NS	Yes
	110	M-NS	No
	135	M-NS	No
	502	F-S	No
	504	F-S	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629992

Draft 1: 24 July 2002

Page 14637 of 15132

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 91 of 111)

Question	Subject Number	Subject Classification ^a	Response
40: On which of the last 3 days were you exposed to the tobacco smoke in this VEHICLE (from Question 39)? Think of Day 1 as the beginning of the 3 days and Day 3 as yesterday.			
For Vehicle Number 1			
Day 2	002	F-S	No
	004	F-S	Yes
	005	F-S	Yes
	012	F-S	Yes
	021	F-S	Yes
	023	F-S	No
	025	F-S	Yes
	026	F-S	No
	029	F-S	Yes
	030	F-S	No
	032	F-S	No
	038	M-S	No
	040	M-S	No
	048	M-S	Yes
	058	M-S	Yes
	068	M-S	Yes
	080	F-NS	No
	110	M-NS	No
	135	M-NS	No
	502	F-S	No
	504	F-S	No
Day 3	002	F-S	Yes
	004	F-S	Yes
	005	F-S	Yes
	012	F-S	No
	021	F-S	No
	023	F-S	Yes
	025	F-S	No
	026	F-S	Yes
	029	F-S	No
	030	F-S	No
	032	F-S	Yes
	038	M-S	No
	040	M-S	Yes

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 92 of 111)

Question	Subject Number	Subject Classification ^a	Response
40: On which of the last 3 days were you exposed to the tobacco smoke in this VEHICLE (from Question 39)? Think of Day 1 as the beginning of the 3 days and Day 3 as yesterday.			
For Vehicle Number 1			
Day 3	048	M-S	Yes
	058	M-S	No
	068	M-S	No
	080	F-NS	No
	110	M-NS	Yes
	135	M-NS	Yes
	502	F-S	Yes
	504	F-S	Yes
For Vehicle Number 2			
Day 1	002	F-S	No
Day 2	002	F-S	Yes
Day 3	002	F-S	Yes
41: In the last 3 days, approximately how many hours were you in this VEHICLE (from Question 39) while you were exposed to the tobacco smoke of others?			
For Vehicle Number 1			
	002	F-S	4
	004	F-S	3
	005	F-S	2 1/2
	012	F-S	6
	021	F-S	1/2
	023	F-S	2
	025	F-S	3
	026	F-S	1/2
	029	F-S	1
	030	F-S	2 1/2
	032	F-S	1/2
	038	M-S	3
	040	M-S	1/2
	048	M-S	1 1/2
	058	M-S	2
	068	M-S	1
	080	F-NS	1
	110	M-NS	1 1/2

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 93 of 111)

Question	Subject Number	Subject Classification ^a	Response
41: In the last 3 days, approximately how many hours were you in this VEHICLE (from Question 39) while you were exposed to the tobacco smoke of others?			
For Vehicle Number 1	135	M-NS	1/2
	502	F-S	1 1/2
	504	F-S	1
For Vehicle Number 2	002	F-S	1
42: Would you say that the amount of tobacco smoke from others in this VEHICLE (from Question 39) was usually light, moderate, or heavy during the last 3 days?			
For Vehicle Number 1	002	F-S	Moderate
	004	F-S	Light
	005	F-S	Light
	012	F-S	Moderate
	021	F-S	Light
	023	F-S	Moderate
	025	F-S	Light
	026	F-S	Light
	029	F-S	Moderate
	030	F-S	Moderate
	032	F-S	Light
	038	M-S	Light
	040	M-S	Light
	048	M-S	Moderate
	058	M-S	Heavy
	068	M-S	Moderate
	080	F-NS	Light
	110	M-NS	Moderate
	135	M-NS	Light
	502	F-S	Light
	504	F-S	Light
For Vehicle Number 2	002	F-S	Light
43: Thinking about just the past 3 days, have you been exposed to the tobacco smoke of others, someplace other than those places that we have already talked about?			
	001	F-S	Yes
	002	F-S	Yes

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 94 of 111)

Question	Subject Number	Subject Classification ^a	Response
43: Thinking about just the past 3 days, have you been exposed to the tobacco smoke of others, someplace other than those places that we have already talked about?	003	F-S	Yes
	004	F-S	Yes
	005	F-S	No
	006	F-S	No
	007	F-S	No
	008	F-S	No
	009	F-S	No
	011	F-S	Yes
	012	F-S	No
	013	F-S	Yes
	014	F-S	No
	015	F-S	No
	016	F-S	Yes
	017	F-S	Yes
	018	F-S	No
	019	F-S	No
	020	F-S	No
	021	F-S	No
	022	F-S	Yes
	023	F-S	No
	024	F-S	Yes
	025	F-S	Yes
	026	F-S	Yes
	027	F-S	No
	028	F-S	Yes
	029	F-S	Yes
	030	F-S	Yes
	031	F-S	No
	032	F-S	Yes
	033	F-S	Yes
	034	F-S	No
	035	F-S	No
	036	M-S	No
	037	M-S	Yes
	038	M-S	No
	039	M-S	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 95 of 111)

Question	Subject Number	Subject Classification ^a	Response
43: Thinking about just the past 3 days, have you been exposed to the tobacco smoke of others, someplace other than those places that we have already talked about?	040	M-S	No
	041	M-S	No
	042	M-S	Yes
	043	M-S	No
	044	M-S	No
	045	M-S	Yes
	046	M-S	Yes
	047	M-S	Yes
	048	M-S	Yes
	049	M-S	No
	050	M-S	No
	052	M-S	Yes
	054	M-S	No
	055	M-S	No
	056	M-S	No
	057	M-S	No
	058	M-S	No
	059	M-S	Yes
	060	M-S	No
	061	M-S	Yes
	062	M-S	No
	063	M-S	Yes
	065	M-S	Yes
	067	M-S	Yes
	068	M-S	Yes
	069	M-S	No
	071	F-NS	No
	072	F-NS	No
	073	F-NS	No
	074	F-NS	No
	075	F-NS	No
	076	F-NS	No
	077	F-NS	No
	078	F-NS	No
	079	F-NS	No
	080	F-NS	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629997

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 96 of 111)

Question	Subject Number	Subject Classification ^a	Response
43: Thinking about just the past 3 days, have you been exposed to the tobacco smoke of others, someplace other than those places that we have already talked about?	081	F-NS	No
	082	F-NS	Yes
	083	F-NS	No
	084	F-NS	Yes
	085	F-NS	No
	086	F-NS	Yes
	087	F-NS	Yes
	088	F-NS	No
	089	F-NS	No
	090	F-NS	No
	091	F-NS	Yes
	092	F-NS	No
	093	F-NS	No
	094	F-NS	No
	095	F-NS	No
	096	F-NS	Yes
	097	F-NS	No
	098	F-NS	No
	099	F-NS	No
	100	F-NS	No
	101	F-NS	No
	102	F-NS	No
	103	F-NS	Yes
	104	M-NS	No
	105	M-NS	Yes
	106	M-NS	Yes
	107	M-NS	No
	108	M-NS	Yes
	109	M-NS	No
	110	M-NS	Yes
	111	M-NS	No
	112	M-NS	Yes
	114	M-NS	No
	115	M-NS	No
	116	M-NS	No
	117	M-NS	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006629998

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 97 of 111)

Question	Subject Number	Subject Classification ^a	Response
43: Thinking about just the past 3 days, have you been exposed to the tobacco smoke of others, someplace other than those places that we have already talked about?	118	M-NS	Yes
	119	M-NS	No
	120	M-NS	No
	121	M-NS	Yes
	122	M-NS	Yes
	123	M-NS	Yes
	124	M-NS	Yes
	125	M-NS	No
	126	M-NS	Yes
	127	M-NS	No
	128	M-NS	No
	129	M-NS	No
	130	M-NS	No
	131	M-NS	No
	132	M-NS	No
	133	M-NS	No
	134	M-NS	No
	135	M-NS	Yes
	500	F-NS	Yes
	501	F-NS	No
	502	F-S	No
	503	F-S	Yes
	504	F-S	No
	505	F-NS	No
	506	F-S	Yes
44: In the past 3 days, how many places have you gone where you were exposed to the tobacco smoke of others?	001	F-S	1
	002	F-S	1
	003	F-S	1
	004	F-S	1
	011	F-S	1
	013	F-S	1
	016	F-S	1
	017	F-S	2
	022	F-S	1

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 98 of 111)

Question	Subject Number	Subject Classification ^a	Response
44: In the past 3 days, how many places have you gone where you were exposed to the tobacco smoke of others?	024	F-S	1
	025	F-S	1
	026	F-S	2
	028	F-S	2
	029	F-S	1
	030	F-S	1
	032	F-S	1
	033	F-S	1
	037	M-S	1
	042	M-S	2
	045	M-S	1
	046	M-S	1
	047	M-S	1
	048	M-S	1
	052	M-S	1
	059	M-S	2
	061	M-S	1
	063	M-S	1
	065	M-S	1
	067	M-S	1
	068	M-S	1
	082	F-NS	1
	084	F-NS	1
	086	F-NS	1
	087	F-NS	1
	091	F-NS	1
	096	F-NS	1
	103	F-NS	4
	105	M-NS	1
	106	M-NS	1
	108	M-NS	1
	110	M-NS	3
	112	M-NS	2
	118	M-NS	1
	121	M-NS	1
	122	M-NS	1

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630000

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 99 of 111)

Question	Subject Number	Subject Classification ^a	Response
44: In the past 3 days, how many places have you gone where you were exposed to the tobacco smoke of others?	123	M-NS	1
	124	M-NS	1
	126	M-NS	1
	135	M-NS	2
	500	F-NS	2
	503	F-S	1
45: What type of place was it? For Place Number 1	506	F-S	3
	001	F-S	RESTAURANT
	002	F-S	RESTAURANT
	003	F-S	FRIENDS APARTMENT
	004	F-S	RESTAURANT
	011	F-S	CASINO
	013	F-S	BAR
	016	F-S	RESTAURANT
	017	F-S	FRIENDS HOUSE
	022	F-S	FRIENDS HOUSE
	024	F-S	OUTSIDE OF WORK BUILDING
	025	F-S	BINGO
	026	F-S	RESTAURANT/BAR
	028	F-S	BAR
	029	F-S	RESTAURANT
	030	F-S	RESTAURANT
	032	F-S	BAR
	033	F-S	BAR
	037	M-S	BAR
	042	M-S	BAR
	045	M-S	BAR
	046	M-S	BAR
	047	M-S	AT WORK
	048	M-S	BAR
	052	M-S	BAR
	059	M-S	RESTAURANT
	061	M-S	DINER

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 100 of 111)

Question	Subject Number	Subject Classification ^a	Response
45: What type of place was it? For Place Number 1	063	M-S	FRIENDS HOUSE
	065	M-S	RESTAURANT
	067	M-S	BAR
	068	M-S	BAR
	082	F-NS	RELATIVES HOUSE
	084	F-NS	SOMEONE ELSE'S HOME
	086	F-NS	OUTDOORS NEXT TO A WEDDING RECEPTION
	087	F-NS	RESTAURANT
	091	F-NS	BINGO HALL
	096	F-NS	BAR
	103	F-NS	BAR
	105	M-NS	BAR
	106	M-NS	BAR
	108	M-NS	BAR
	110	M-NS	RESTAURANT
	112	M-NS	BAR
	118	M-NS	BAR
	121	M-NS	RECEPTION HALL
	122	M-NS	FRIENDS HOUSE
	123	M-NS	RESTAURANT
	124	M-NS	MEMORIAL UNION/RESTAURANT
	126	M-NS	OUTDOOR AUCTION
	135	M-NS	RESTAURANT/BAR
	500	F-NS	BAR
	503	F-S	BAR
	506	F-S	SOMEONE'S HOUSE
For Place Number 2	017	F-S	BAR
	026	F-S	RESTAURANT
	028	F-S	RESTAURANT
	042	M-S	BAR
	059	M-S	RESTAURANT/BAR
	103	F-NS	BAR
	110	M-NS	RESTAURANT
	112	M-NS	BAR

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 101 of 111)

Question	Subject Number	Subject Classification ^a	Response
45: What type of place was it? For Place Number 2	135	M-NS	RESTAURANT/BAR
	500	F-NS	BAR
	506	F-S	CONCERT
For Place Number 3	103	F-NS	BAR
	110	M-NS	RESTAURANT
	506	F-S	BAR
For Place Number 4	103	F-NS	BAR
46: On which of the last 3 days were you exposed to the tobacco smoke of others in this PLACE (from Question 45)? Think of Day 1 as the beginning of the 3 days and Day 3 as yesterday. For Place Number 1 Day 1	001	F-S	No
	002	F-S	No
	003	F-S	No
	004	F-S	Yes
	011	F-S	No
	013	F-S	No
	016	F-S	Yes
	017	F-S	Yes
	022	F-S	Yes
	024	F-S	Yes
	025	F-S	Yes
	026	F-S	No
	028	F-S	Yes
	029	F-S	Yes
	030	F-S	No
	032	F-S	No
	033	F-S	Yes
	037	M-S	No
	042	M-S	No
	045	M-S	No
	046	M-S	No
	047	M-S	No
	048	M-S	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 102 of 111)

Question	Subject Number	Subject Classification ^a	Response
46: On which of the last 3 days were you exposed to the tobacco smoke of others in this PLACE (from Question 45)? Think of Day 1 as the beginning of the 3 days and Day 3 as yesterday.			
For Place Number 1			
Day 1	052	M-S	No
	059	M-S	Yes
	061	M-S	No
	063	M-S	No
	065	M-S	No
	067	M-S	No
	068	M-S	No
	082	F-NS	No
	084	F-NS	Yes
	086	F-NS	Yes
	087	F-NS	Yes
	091	F-NS	No
	096	F-NS	No
	103	F-NS	No
	105	M-NS	No
	106	M-NS	No
	108	M-NS	No
	110	M-NS	Yes
	112	M-NS	No
	118	M-NS	Yes
	121	M-NS	No
	122	M-NS	No
	123	M-NS	Yes
	124	M-NS	Yes
	126	M-NS	No
	135	M-NS	Yes
	500	F-NS	Yes
	503	F-S	No
	506	F-S	No
Day 2	001	F-S	Yes
	002	F-S	No
	003	F-S	Yes
	004	F-S	Yes
	011	F-S	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 103 of 111)

Question	Subject Number	Subject Classification ^a	Response
46: On which of the last 3 days were you exposed to the tobacco smoke of others in this PLACE (from Question 45)? Think of Day 1 as the beginning of the 3 days and Day 3 as yesterday. For Place Number 1 Day 2	013	F-S	Yes
	016	F-S	No
	017	F-S	No
	022	F-S	No
	024	F-S	Yes
	025	F-S	Yes
	026	F-S	No
	028	F-S	No
	029	F-S	No
	030	F-S	Yes
	032	F-S	No
	033	F-S	Yes
	037	M-S	No
	042	M-S	Yes
	045	M-S	Yes
	046	M-S	No
	047	M-S	Yes
	048	M-S	Yes
	052	M-S	Yes
	059	M-S	No
	061	M-S	Yes
	063	M-S	No
	065	M-S	No
	067	M-S	No
	068	M-S	No
	082	F-NS	Yes
	084	F-NS	No
	086	F-NS	Yes
	087	F-NS	No
	091	F-NS	Yes
	096	F-NS	No
	103	F-NS	Yes
	105	M-NS	No
	106	M-NS	Yes
	108	M-NS	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 104 of 111)

Question	Subject Number	Subject Classification ^a	Response
46: On which of the last 3 days were you exposed to the tobacco smoke of others in this PLACE (from Question 45)? Think of Day 1 as the beginning of the 3 days and Day 3 as yesterday.			
For Place Number 1			
Day 2	110	M-NS	Yes
	112	M-NS	Yes
	118	M-NS	Yes
	121	M-NS	Yes
	122	M-NS	No
	123	M-NS	No
	124	M-NS	No
	126	M-NS	Yes
	135	M-NS	No
	500	F-NS	No
	503	F-S	Yes
	506	F-S	Yes
Day 3	001	F-S	No
	002	F-S	Yes
	003	F-S	No
	004	F-S	Yes
	011	F-S	Yes
	013	F-S	No
	016	F-S	No
	017	F-S	No
	022	F-S	No
	024	F-S	No
	025	F-S	Yes
	026	F-S	Yes
	028	F-S	No
	029	F-S	No
	030	F-S	No
	032	F-S	Yes
	033	F-S	Yes
	037	M-S	Yes
	042	M-S	Yes
	045	M-S	No
	046	M-S	Yes
	047	M-S	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 105 of 111)

Question	Subject Number	Subject Classification ^a	Response
46: On which of the last 3 days were you exposed to the tobacco smoke of others in this PLACE (from Question 45)? Think of Day 1 as the beginning of the 3 days and Day 3 as yesterday.			
For Place Number 1			
Day 3	048	M-S	No
	052	M-S	No
	059	M-S	Yes
	061	M-S	No
	063	M-S	Yes
	065	M-S	Yes
	067	M-S	Yes
	068	M-S	Yes
	082	F-NS	Yes
	084	F-NS	No
	086	F-NS	No
	087	F-NS	No
	091	F-NS	No
	096	F-NS	Yes
	103	F-NS	No
	105	M-NS	Yes
	106	M-NS	No
	108	M-NS	Yes
	110	M-NS	Yes
	112	M-NS	No
	118	M-NS	Yes
	121	M-NS	No
	122	M-NS	Yes
	123	M-NS	Yes
	124	M-NS	No
	126	M-NS	No
	135	M-NS	No
	500	F-NS	No
	503	F-S	No
	506	F-S	No
For Place Number 2			
Day 1	017	F-S	No
	026	F-S	No
	028	F-S	No
	042	M-S	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-14
Weekly Survey by Question; Week 6
(Page 106 of 111)

Question	Subject Number	Subject Classification ^a	Response
46: On which of the last 3 days were you exposed to the tobacco smoke of others in this PLACE (from Question 45)? Think of Day 1 as the beginning of the 3 days and Day 3 as yesterday.			
For Place Number 2			
Day 1	059	M-S	No
	103	F-NS	No
	110	M-NS	Yes
	112	M-NS	No
	135	M-NS	Yes
	500	F-NS	Yes
	506	F-S	No
Day 2	017	F-S	Yes
	026	F-S	No
	028	F-S	Yes
	042	M-S	Yes
	059	M-S	No
	103	F-NS	Yes
	110	M-NS	Yes
	112	M-NS	Yes
	135	M-NS	No
	500	F-NS	No
	506	F-S	Yes
Day 3	017	F-S	No
	026	F-S	Yes
	028	F-S	No
	042	M-S	Yes
	059	M-S	Yes
	103	F-NS	No
	110	M-NS	Yes
	112	M-NS	No
	135	M-NS	No
	500	F-NS	No
	506	F-S	No
For Place Number 3			
Day 1	103	F-NS	No
	110	M-NS	Yes
	506	F-S	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630008

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 107 of 111)

Question	Subject Number	Subject Classification ^a	Response
46: On which of the last 3 days were you exposed to the tobacco smoke of others in this PLACE (from Question 45)? Think of Day 1 as the beginning of the 3 days and Day 3 as yesterday.			
For Place Number 3			
Day 2	103	F-NS	Yes
	110	M-NS	Yes
	506	F-S	Yes
Day 3	103	F-NS	No
	110	M-NS	Yes
	506	F-S	No
For Place Number 4			
Day 1	103	F-NS	No
Day 2	103	F-NS	Yes
Day 3	103	F-NS	No
47: During the last 3 days, approximately how many hours were you in PLACE (from Question 45) where you were exposed to the tobacco smoke of others?			
For Place Number 1			
	001	F-S	1 1/2
	002	F-S	1
	003	F-S	3
	004	F-S	4
	011	F-S	4
	013	F-S	5
	016	F-S	2
	017	F-S	4
	022	F-S	3 1/2
	024	F-S	1 1/2
	025	F-S	5 1/2
	026	F-S	1 1/2
	028	F-S	8
	029	F-S	2
	030	F-S	2
	032	F-S	3
	033	F-S	12
	037	M-S	6
	042	M-S	2

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 108 of 111)

Question	Subject Number	Subject Classification ^a	Response
47: During the last 3 days, approximately how many hours were you in PLACE (from Question 45) where you were exposed to the tobacco smoke of others?			
For Place Number 1			
	045	M-S	3
	046	M-S	5
	047	M-S	1/2
	048	M-S	4
	052	M-S	2
	059	M-S	10
	061	M-S	1
	063	M-S	2 1/2
	065	M-S	5 1/2
	067	M-S	1 1/2
	068	M-S	2
	082	F-NS	4
	084	F-NS	1 1/2
	086	F-NS	2 1/2
	087	F-NS	3
	091	F-NS	3
	096	F-NS	4 1/2
	103	F-NS	1
	105	M-NS	1
	106	M-NS	3
	108	M-NS	4
	110	M-NS	1
	112	M-NS	3
	118	M-NS	15
	121	M-NS	5
	122	M-NS	1
	123	M-NS	1 1/2
	124	M-NS	1/2
	126	M-NS	1 1/2
	135	M-NS	2
	500	F-NS	11
	503	F-S	1
	506	F-S	1/2
For Place Number 2			
	017	F-S	2

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630010

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 109 of 111)

Question	Subject Number	Subject Classification ^a	Response
47: During the last 3 days, approximately how many hours were you in PLACE (from Question 45) where you were exposed to the tobacco smoke of others? For Place Number 2	026	F-S	1 1/2
	028	F-S	2
	042	M-S	2
	059	M-S	6
	103	F-NS	1
	110	M-NS	1
	112	M-NS	1 1/2
	135	M-NS	2
	500	F-NS	11
	506	F-S	3
For Place Number 3	103	F-NS	1
	110	M-NS	1
	506	F-S	1
For Place Number 4	103	F-NS	1
48: Would you say that the amount of tobacco smoke in the PLACE (from Question 45) was usually light, moderate, or heavy during the last 3 days? For Place Number 1	001	F-S	Light
	002	F-S	Light
	003	F-S	Light
	004	F-S	Light
	011	F-S	Light
	013	F-S	Heavy
	016	F-S	Light
	017	F-S	Light
	022	F-S	Light
	024	F-S	Light
	025	F-S	Heavy
	026	F-S	Light
	028	F-S	Moderate
	029	F-S	Light
	030	F-S	Light
	032	F-S	Moderate

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 110 of 111)

Question	Subject Number	Subject Classification ^a	Response
48: Would you say that the amount of tobacco smoke in the PLACE (from Question 45) was usually light, moderate, or heavy during the last 3 days? For Place Number 1	033	F-S	Heavy
	037	M-S	Light
	042	M-S	Light
	045	M-S	Moderate
	046	M-S	Heavy
	047	M-S	Light
	048	M-S	Heavy
	052	M-S	Moderate
	059	M-S	Light
	061	M-S	Light
	063	M-S	Heavy
	065	M-S	Light
	067	M-S	Heavy
	068	M-S	Moderate
	082	F-NS	Light
	084	F-NS	Light
	086	F-NS	Light
	087	F-NS	Light
	091	F-NS	Light
	096	F-NS	Light
	103	F-NS	Heavy
	105	M-NS	Moderate
	106	M-NS	Heavy
	108	M-NS	Moderate
	110	M-NS	Moderate
	112	M-NS	Light
	118	M-NS	Moderate
	121	M-NS	Light
	122	M-NS	Light
	123	M-NS	Moderate
	124	M-NS	Light
	126	M-NS	Light
	135	M-NS	Light
	500	F-NS	Light
	503	F-S	Moderate

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630012

Listing 16.5-14
Weekly Survey by Question: Week 6
(Page 111 of 111)

Question	Subject Number	Subject Classification ^a	Response
48: Would you say that the amount of tobacco smoke in the PLACE (from Question 45) was usually light, moderate, or heavy during the last 3 days?			
For Place Number 1	506	F-S	Light
For Place Number 2	017	F-S	Moderate
	026	F-S	Light
	028	F-S	Light
	042	M-S	Light
	059	M-S	Light
	103	F-NS	Heavy
	110	M-NS	Moderate
	112	M-NS	Light
	135	M-NS	Light
	500	F-NS	Light
	506	F-S	Heavy
For Place Number 3	103	F-NS	Heavy
	110	M-NS	Moderate
	506	F-S	Moderate
For Place Number 4	103	F-NS	Heavy

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-15
Non-Smoker Diaries by Subject
(Page 1 of 16)

Subject Number	Subject Classification ^a	Timepoint	Date	Location	Number of Hours Exposed	Number of Cigarettes Smoked by Others	Intensity ^b
071	F-NS	Week 1	08-MAY-2001	Outside	1	0.5	1
		Week 2	18-MAY-2001	No Exposure			
		Week 3	22-MAY-2001	No Exposure			
		Week 6	12-JUN-2001	No Exposure			
072	F-NS	Week 1	06-MAY-2001	Outside	1	1	1
			07-MAY-2001	Outside	1	1	1
		Week 2	11-MAY-2001	Outside	1	1	1
		Week 3	22-MAY-2001	No Exposure			
		Week 6	12-JUN-2001	No Exposure			
073	F-NS	Week 1	06-MAY-2001	Restaurant	1	Unknown	1
		Week 2	16-MAY-2001	No Exposure			
		Week 3	22-MAY-2001	No Exposure			
		Week 6	13-JUN-2001	No Exposure			
074	F-NS	Week 1	06-MAY-2001	Home	2	3	1
			06-MAY-2001	Restaurant	1	2	1
			07-MAY-2001	Home	1	0.5	1
			08-MAY-2001	Home	1	0.5	1
			11-MAY-2001	Home	1	1	1
		Week 2	12-MAY-2001	Home	1	1	1
			13-MAY-2001	Home	1	1	1
			13-MAY-2001	Home	1	2	2
			20-MAY-2001	Home	1	2	1
		Week 3					
		Week 6	11-JUN-2001	No Exposure			
075	F-NS	Week 1	08-MAY-2001	Outside	1	1	1
		Week 2	14-MAY-2001	No Exposure			
		Week 3	23-MAY-2001	No Exposure			
		Week 6	14-JUN-2001	No Exposure			
076	F-NS	Week 1	11-MAY-2001	No Exposure			

^a Subject Classification: M-NS=Male, Non-Smoker; F-NS=Female, Non-Smoker.

^b 1=Light, 2=Moderate, and 3=Heavy.

Listing 16.5-15
Non-Smoker Diaries by Subject
(Page 2 of 16)

Subject Number	Subject Classification ^a	Timepoint	Date	Location	Number of Hours Exposed	Number of Cigarettes Smoked by Others	Intensity ^b
076	F-NS	Week 2	20-MAY-2001	No Exposure			
		Week 3	25-MAY-2001	No Exposure			
		Week 6	11-JUN-2001	No Exposure			
077	F-NS	Week 1	09-MAY-2001	No Exposure			
		Week 2	13-MAY-2001	Kitchen	1	2	1
		Week 3	21-MAY-2001	No Exposure			
		Week 6	11-JUN-2001	No Exposure			
078	F-NS	Week 1	08-MAY-2001	Outside	1	2	2
		Week 2	13-MAY-2001	Casino	1	4	2
		Week 3	21-MAY-2001	No Exposure			
		Week 6	13-JUN-2001	No Exposure			
079	F-NS	Week 1	09-MAY-2001	No Exposure			
		Week 2	14-MAY-2001	No Exposure			
		Week 3	21-MAY-2001	No Exposure			
		Week 6	11-JUN-2001	No Exposure			
080	F-NS	Week 1	06-MAY-2001	Car	1	2	1
		Week 2	14-MAY-2001	Car	1	1	1
		Week 3	21-MAY-2001	No Exposure			
		Week 6	08-JUN-2001	Car	1	2	1
081	F-NS	Week 1	09-MAY-2001	No Exposure			
		Week 2	14-MAY-2001	No Exposure			
		Week 3	21-MAY-2001	No Exposure			
		Week 6	11-JUN-2001	No Exposure			
082	F-NS	Week 1	09-MAY-2001	No Exposure			
		Week 2	19-MAY-2001	Car	1	2	1
		Week 3	25-MAY-2001	No Exposure			

^a Subject Classification: M-NS=Male, Non-Smoker; F-NS=Female, Non-Smoker.

^b 1=Light, 2=Moderate, and 3=Heavy.

Listing 16.5-15
Non-Smoker Diaries by Subject
(Page 3 of 16)

Subject Number	Subject Classification ^a	Timepoint	Date	Location	Number of Hours Exposed	Number of Cigarettes Smoked by Others	Intensity ^b
082	F-NS	Week 6	15-JUN-2001	House	2	3	1
			16-JUN-2001	House	2	6	2
083	F-NS	Week 1	10-MAY-2001	No Exposure			
		Week 2	15-MAY-2001	No Exposure			
		Week 3	25-MAY-2001	No Exposure			
		Week 6	12-JUN-2001	No Exposure			
084	F-NS	Week 1	08-MAY-2001	House	1	0.5	1
		Week 2	13-MAY-2001	House & car	2	6	1
			13-MAY-2001	House	1	2	1
		Week 3	13-MAY-2001	Car	1	2	1
			23-MAY-2001	No Exposure			
		Week 6	11-JUN-2001	House	2	4	1
085	F-NS	Week 1	10-MAY-2001	No Exposure			
		Week 2	16-MAY-2001	No Exposure			
		Week 3	23-MAY-2001	No Exposure			
		Week 6	11-JUN-2001	No Exposure			
086	F-NS	Week 1	08-MAY-2001	Bar	1	17	2
		Week 2	12-MAY-2001		3	5	1
		Week 3	25-MAY-2001	No Exposure			
		Week 6	09-JUN-2001	Wedding reception	1	3	1
			10-JUN-2001	Outdoors	1	1	1
087	F-NS	Week 1	07-MAY-2001	Restaurant/Bar	3	40	1
			08-MAY-2001	Restaurant	3	30	1
		Week 2	12-MAY-2001	Restaurant/Bar	1	30	2
		Week 3	19-MAY-2001	Restaurant/Bar	2	18	1
		Week 6	08-JUN-2001	Restaurant/Bar	3	32	1
088	F-NS	Week 1	06-MAY-2001	Casino	2	8	1

^a Subject Classification: M-NS=Male, Non-Smoker; F-NS=Female, Non-Smoker.

^b 1=Light, 2=Moderate, and 3=Heavy.

Listing 16.5-15
Non-Smoker Diaries by Subject
(Page 4 of 16)

Subject Number	Subject Classification ^a	Timepoint	Date	Location	Number of Hours Exposed	Number of Cigarettes Smoked by Others	Intensity ^b
088	F-NS	Week 2	14-MAY-2001	No Exposure			
		Week 3	23-MAY-2001	No Exposure			
		Week 6	11-JUN-2001	No Exposure			
089	F-NS	Week 1	10-MAY-2001	No Exposure			
		Week 2	16-MAY-2001	No Exposure			
		Week 3	22-MAY-2001	No Exposure			
		Week 6	11-JUN-2001	No Exposure			
090	F-NS	Week 1	10-MAY-2001	No Exposure			
		Week 2	14-MAY-2001	No Exposure			
		Week 3	24-MAY-2001	No Exposure			
		Week 6	12-JUN-2001	No Exposure			
091	F-NS	Week 1	07-MAY-2001	Bar	1	30	2
			08-MAY-2001	Bingo	5	10	1
		Week 2	12-MAY-2001	Bar	1	10	1
			13-MAY-2001	Bingo	4	8	1
		Week 3	20-MAY-2001	Bingo	4	8	1
		Week 6	07-JUN-2001	Bingo	3	3	1
			10-JUN-2001		4	12	1
092	F-NS	Week 1	08-MAY-2001	Garage	2	6	2
			09-MAY-2001	Garage	1	3	2
		Week 2	15-MAY-2001	No Exposure			
		Week 3	21-MAY-2001	No Exposure			
		Week 6	14-JUN-2001	No Exposure			
093	F-NS	Week 1	10-MAY-2001	No Exposure			
		Week 2	16-MAY-2001	No Exposure			
		Week 3	22-MAY-2001	No Exposure			
		Week 6	13-JUN-2001	No Exposure			

^a Subject Classification: M-NS=Male, Non-Smoker; F-NS=Female, Non-Smoker.

^b 1=Light, 2=Moderate, and 3=Heavy.

Listing 16.5-15
Non-Smoker Diaries by Subject
(Page 5 of 16)

Subject Number	Subject Classification ^a	Timepoint	Date	Location	Number of Hours Exposed	Number of Cigarettes Smoked by Others	Intensity ^b
094	F-NS	Week 1	10-MAY-2001	No Exposure	1	1	1
		Week 2	16-MAY-2001	No Exposure			
		Week 3	20-MAY-2001	Outside			
		Week 6	13-JUN-2001	No Exposure			
095	F-NS	Week 1	09-MAY-2001	No Exposure			
		Week 2	15-MAY-2001	No Exposure			
		Week 3	23-MAY-2001	No Exposure			
		Week 6	12-JUN-2001	No Exposure			
096	F-NS	Week 1	10-MAY-2001	Pedros	2	5	1
		Week 2	12-MAY-2001	Outside	3	25	1-2
		Week 3	21-MAY-2001	No Exposure	2	10	1
		Week 6	16-JUN-2001	Bar			
097	F-NS	Week 1	11-MAY-2001	No Exposure	3	41	1
		Week 2	20-MAY-2001	No Exposure			
		Week 3	25-MAY-2001	No Exposure			
		Week 6	16-JUN-2001	No Exposure			
098	F-NS	Week 1	07-MAY-2001	Outside	1	1	1
		Week 2	15-MAY-2001	No Exposure			
		Week 3	24-MAY-2001	No Exposure			
		Week 6	11-JUN-2001	No Exposure			
099	F-NS	Week 1	09-MAY-2001	No Exposure			
		Week 2	14-MAY-2001	No Exposure			
		Week 3	22-MAY-2001	No Exposure			
		Week 6	11-JUN-2001	No Exposure			
100	F-NS	Week 1	09-MAY-2001	Bar	2	10	1

^a Subject Classification: M-NS=Male, Non-Smoker; F-NS=Female, Non-Smoker.

^b 1=Light, 2=Moderate, and 3=Heavy.

Listing 16.5-15
Non-Smoker Diaries by Subject
(Page 6 of 16)

Subject Number	Subject Classification ^a	Timepoint	Date	Location	Number of Hours Exposed	Number of Cigarettes Smoked by Others	Intensity ^b
100	F-NS	Week 2	18-MAY-2001	No Exposure			
		Week 3	23-MAY-2001	No Exposure			
		Week 6	14-JUN-2001	No Exposure			
101	F-NS	Week 1	11-MAY-2001	No Exposure			
		Week 2	14-MAY-2001	No Exposure			
		Week 3	25-MAY-2001	No Exposure			
		Week 6	17-JUN-2001	No Exposure			
102	F-NS	Week 1	09-MAY-2001	No Exposure			
		Week 2	20-MAY-2001	No Exposure			
		Week 3	25-MAY-2001	No Exposure			
		Week 6	12-JUN-2001	No Exposure			
103	F-NS	Week 1	10-MAY-2001	No Exposure			
		Week 2	18-MAY-2001	Bar	3	15	1
			18-MAY-2001	Bar	1	10	2
			18-MAY-2001	Bar	2	60	3
		Week 3	24-MAY-2001	No Exposure			
		Week 6	16-JUN-2001	Bar	2	40	3
			17-JUN-2001	Bar	2	40	3
104	M-NS	Week 1	06-MAY-2001	Porch	1	2	1
		Week 2	17-MAY-2001	No Exposure			
		Week 3	22-MAY-2001	No Exposure			
		Week 6	10-JUN-2001	Porch	1	2	1
105	M-NS	Week 1	08-MAY-2001	Bar	2	20	1
		Week 2	12-MAY-2001	Bar	2	3	1
			13-MAY-2001	Bar	3	15	2
		Week 3	23-MAY-2001	No Exposure			
		Week 6	13-JUN-2001	Bar	1	2	3

^a Subject Classification: M-NS=Male, Non-Smoker; F-NS=Female, Non-Smoker.

^b 1=Light, 2=Moderate, and 3=Heavy.

Listing 16.5-15
Non-Smoker Diaries by Subject
(Page 7 of 16)

Subject Number	Subject Classification ^a	Timepoint	Date	Location	Number of Hours Exposed	Number of Cigarettes Smoked by Others	Intensity ^b
106	M-NS	Week 1	10-MAY-2001	Outside	1	1	1
		Week 2	16-MAY-2001	Bar	2	4	2
		Week 3	21-MAY-2001	Bar	2	20	3
		Week 6	08-JUN-2001	Bar	1	Lots	3
			09-JUN-2001	Bar	2	Lots	3
107	M-NS	Week 1	09-MAY-2001	Bar	2	40	2
			09-MAY-2001	Arca	3	60	2
		Week 2	17-MAY-2001	No Exposure			
		Week 3	22-MAY-2001	Work	1	1	1
		Week 6	13-JUN-2001	Bar	2	50	3
108	M-NS	Week 1	06-MAY-2001	Bar	3	30	1
			06-MAY-2001	Ft. McCoy	2	12	1
			08-MAY-2001	Bar	1	20	2
			08-MAY-2001	Bar	1	35	3
			09-MAY-2001	Bar	2	70	3
		Week 2	12-MAY-2001	Bar	3	40	2
			12-MAY-2001	Bar	1	30	3
			12-MAY-2001	Bar	1	4	1
			13-MAY-2001	Bar	2	60	3
			13-MAY-2001	Bar	2	60	3
		Week 3	19-MAY-2001	Bar	1	10	1
			19-MAY-2001	Bar	2	30	2
			21-MAY-2001	House	1	2	1
		Week 6	12-JUN-2001	Bar	2	40	2
			13-JUN-2001	Bar	2	60	2
109	M-NS	Week 1	06-MAY-2001	Work van	2	2	1
			06-MAY-2001	Office	1	10	2
		Week 2	13-MAY-2001	Home	1	1	1
		Week 3	21-MAY-2001	No Exposure			

^a Subject Classification: M-NS=Male, Non-Smoker, F-NS=Female, Non-Smoker.

^b 1=Light, 2=Moderate, and 3=Heavy.

Listing 16.5-15
Non-Smoker Diaries by Subject
(Page 8 of 16)

Subject Number	Subject Classification ^a	Timepoint	Date	Location	Number of Hours Exposed	Number of Cigarettes Smoked by Others	Intensity ^b
109	M-NS	Week 6	11-JUN-2001	No Exposure			
110	M-NS	Week 1	07-MAY-2001	Home	8	37	2
			07-MAY-2001	Home	1	2	1
			07-MAY-2001	Home	5	0	1
			07-MAY-2001	Travel to work	1	0	1
			07-MAY-2001	Work	8	0	1
			07-MAY-2001	Bed	1	0	1
			08-MAY-2001	Home	3	18	2
			08-MAY-2001	Home	1	3	1
			08-MAY-2001	Home	5	0	1
			08-MAY-2001	Drive to work	1	0	1
			08-MAY-2001	Work	12	9	1
			08-MAY-2001	Drive home	1	0	1
			08-MAY-2001	Asleep	1	0	1
			09-MAY-2001	Home	8	37	2
			09-MAY-2001	Asleep	7	0	1
			09-MAY-2001	Drive to office	1	0	1
			09-MAY-2001	Office	8	0	1
			10-MAY-2001	Home	1	4	2
			10-MAY-2001	Home-asleep	6	0	1
			10-MAY-2001	Drive to Madison	2	0	1
		Week 2	15-MAY-2001	Restaurant	1	@ 10/12	2
			15-MAY-2001	Restaurant	2	40	2
			15-MAY-2001	Hotel lounge	2	60	3
			15-MAY-2001	Hotel-Conference	9	0	1
			15-MAY-2001	Hotel-Sleeping	2	0	1
			15-MAY-2001	Hotel-Sleeping	8	0	0/1
			16-MAY-2001	Hotel lounge	3	60	3
			16-MAY-2001	Restaurant	3	26	2
			16-MAY-2001	Hotel room	8	0	1
			16-MAY-2001	Hotel-Conference	10	0	1
			17-MAY-2001	Home	7	31	2
			17-MAY-2001	Hotel	4	30	2
			17-MAY-2001	Hotel-Conference	8	0	1
			17-MAY-2001	Return Home	4	0	1
			17-MAY-2001	Sleeping	1	0	1
			18-MAY-2001	Home	2	8	2
			18-MAY-2001	Home sleeping	5	0	1

^a Subject Classification: M-NS=Male, Non-Smoker; F-NS=Female, Non-Smoker.

^b 1=Light, 2=Moderate, and 3=Heavy.

PM3006630021

Listing 16.5-15
Non-Smoker Diaries by Subject
(Page 9 of 16)

Subject Number	Subject Classification ^a	Timepoint	Date	Location	Number of Hours Exposed	Number of Cigarettes Smoked by Others	Intensity ^b
110	M-NS	Week 3	19-MAY-2001	Home	5	20	2
			19-MAY-2001	Home-sleeping	8	0	1
			19-MAY-2001	Travel to Ft. McCoy	7	0	1
			19-MAY-2001	Home-outside	4	0	1
			20-MAY-2001	Home	6	24	2
			20-MAY-2001	Home-sleeping	9	0	1
			20-MAY-2001	Home-outside	9	0	1
			21-MAY-2001	Car	3	12	2
			21-MAY-2001	Home	3	12	2
			21-MAY-2001	Home-sleeping	7	0	1
			21-MAY-2001	Shopping	1	0	1
			21-MAY-2001	Madison-Business	2	0	1
			21-MAY-2001	Home-alone	1	0	1
			22-MAY-2001	Home	1	5	2
			22-MAY-2001	Home-Sleeping	6	0	1
			22-MAY-2001	Car	2	0	1
		Week 6	09-JUN-2001	Hotel	8	33	2
			09-JUN-2001	Sight seeing	5	30-50	1
			09-JUN-2001	Restaurant	1	10-12	2
			09-JUN-2001	Hotel-sleeping	10	0	1
			10-JUN-2001	Hotel	4	18	2
			10-JUN-2001	Sight seeing	5	40	0.5
			10-JUN-2001	Restaurant	2	@20	2
			10-JUN-2001	Hotel room	3	13	2
			10-JUN-2001	Hotel-sleeping	10	0	1
			11-JUN-2001	Airport	4	18	2
			11-JUN-2001	Car	3	13	2
			11-JUN-2001	Home	1	2	2
			11-JUN-2001	Hotel	6	0	1
			11-JUN-2001	Hotel-sleeping	1	0	1
			11-JUN-2001	Flight to O'Hare	3	0	1
			11-JUN-2001	O'Hare Airport	3	0	1
			11-JUN-2001	Travel on airplane	2	0	1
			11-JUN-2001	Home-sleeping	1	0	1
			12-JUN-2001	Home-sleeping	7	0	1
			12-JUN-2001	Travel to Covance	2	0	1

^a Subject Classification: M-NS=Male, Non-Smoker; F-NS=Female, Non-Smoker.

^b 1=Light, 2=Moderate, and 3=Heavy.

PM3006630022

Listing 16.5-15
Non-Smoker Diaries by Subject
(Page 10 of 16)

Subject Number	Subject Classification ^a	Timepoint	Date	Location	Number of Hours Exposed	Number of Cigarettes Smoked by Others	Intensity ^b
111	M-NS	Week 1	06-MAY-2001	House	2	6	1
			07-MAY-2001	Outside	1	10	1
		Week 2	08-MAY-2001	Office	3	12	2
			12-MAY-2001	Outside	1	1	1
			12-MAY-2001	Bar	3	25	1
		Week 3	13-MAY-2001	Unknown	1	10	1
			18-MAY-2001	Bar	2	20	1
			19-MAY-2001	Outside	4	20	1
			20-MAY-2001	Outside	1	10	1
		Week 6	08-JUN-2001	Office	1	12	1
112	M-NS	Week 1	11-MAY-2001	No Exposure			
		Week 2	15-MAY-2001	No Exposure			
		Week 3	18-MAY-2001	Bar	2	45	2
		Week 6	09-JUN-2001	Bar	3	15	1
113	M-NS	Week 1	07-MAY-2001	Home	4	10	2
			07-MAY-2001	Home	4	5	1
			07-MAY-2001	Car	2	5	2
			07-MAY-2001	Car	1	2	1
			08-MAY-2001	Home	1	1	1
			08-MAY-2001	Home	6	14	2
			09-MAY-2001	Home	3	14	3
			09-MAY-2001	Home	2	5	2
			09-MAY-2001	Car	3	6	2
			09-MAY-2001	Home	2	2	1
			09-MAY-2001	Car	1	1	0
			10-MAY-2001	Home	1	1	1
		Week 2	12-MAY-2001	Home	3	5	1
			12-MAY-2001	Home	7	21	2
			12-MAY-2001	Home	2	10	3
			13-MAY-2001	Home	6	9	1
			13-MAY-2001	Home	5	13	2
			13-MAY-2001	Home	1	4	3
			14-MAY-2001	Home	5	6	1
			14-MAY-2001	Home	6	13	2
			14-MAY-2001	Home	3	12	3
			15-MAY-2001	Home	2	2	1

^a Subject Classification: M-NS=Male, Non-Smoker; F-NS=Female, Non-Smoker.

^b 1=Light, 2=Moderate, and 3=Heavy.

PM3006630023

Listing 16.5-15
Non-Smoker Diaries by Subject
(Page 11 of 16)

Subject Number	Subject Classification ^a	Timepoint	Date	Location	Number of Hours Exposed	Number of Cigarettes Smoked by Others	Intensity ^b
114	M-NS	Week 1	11-MAY-2001	No Exposure			
		Week 2	20-MAY-2001	No Exposure			
		Week 3	24-MAY-2001	No Exposure			
		Week 6	13-JUN-2001	House	1	0.5	1
115	M-NS	Week 1	09-MAY-2001	No Exposure			
		Week 2	18-MAY-2001	No Exposure			
		Week 3	22-MAY-2001	No Exposure			
		Week 6	15-JUN-2001	No Exposure			
116	M-NS	Week 1	09-MAY-2001	No Exposure			
		Week 2	12-MAY-2001	House	1	25	3
		Week 3	21-MAY-2001	No Exposure			
		Week 6	08-JUN-2001	No Exposure			
117	M-NS	Week 1	09-MAY-2001	No Exposure			
		Week 2	16-MAY-2001	No Exposure			
		Week 3	22-MAY-2001	No Exposure			
		Week 6	13-JUN-2001	No Exposure			
118	M-NS	Week 1	07-MAY-2001	Bar	3	70	2
			07-MAY-2001	Bar	2	25	1
			08-MAY-2001	Bar	2	85	3
			08-MAY-2001	Bar	1	25	2
		Week 2	09-MAY-2001	Bar	2	15	1
			12-MAY-2001	Restaurant	1	5	1
			12-MAY-2001	Bar	7	155	3
			13-MAY-2001	Bar	2	40	2
			13-MAY-2001	Bar	2	60	3
			14-MAY-2001	Bar	3	60	2
			14-MAY-2001	Bar	1	10	1
			15-MAY-2001	Bar	2	30	2

^a Subject Classification: M-NS=Male, Non-Smoker; F-NS=Female, Non-Smoker.

^b 1=Light, 2=Moderate, and 3=Heavy.

Listing 16.5-15
Non-Smoker Diaries by Subject
(Page 12 of 16)

Subject Number	Subject Classification ^a	Timepoint	Date	Location	Number of Hours Exposed	Number of Cigarettes Smoked by Others	Intensity ^b
118	M-NS	Week 3	21-MAY-2001	Bar	3	90	3
			21-MAY-2001	Bar	1	20	2
			21-MAY-2001	Bar	1	10	1
			22-MAY-2001	Bar	1	20	2
			22-MAY-2001	Bar	1	10	1
			23-MAY-2001	Bar	2	40	2
			24-MAY-2001	Bar	1	15	2
		Week 6	09-JUN-2001	Bar	4	150	3
			10-JUN-2001	Bar	5	95	2
			10-JUN-2001	Bar	2	20	1
			11-JUN-2001	Bar	3	65	2
			11-JUN-2001	Bar	3	115	3
			11-JUN-2001	Bar	2	20	1
			12-JUN-2001	Bar	2	50	2
119	M-NS	Week 1	09-MAY-2001	No Exposure			
		Week 2	14-MAY-2001	No Exposure			
		Week 3	21-MAY-2001	No Exposure			
		Week 6	12-JUN-2001	No Exposure			
120	M-NS	Week 1	06-MAY-2001	Outside	1	1	1
			07-MAY-2001	Breakroom	1	6	1
			08-MAY-2001	Breakroom	1	5	1
		Week 2	14-MAY-2001	No Exposure			
		Week 3	21-MAY-2001	Breakroom	1	6	1
		Week 6	22-MAY-2001	Breakroom	1	5	1
			11-JUN-2001	No Exposure			
121	M-NS	Week 1	09-MAY-2001	No Exposure			
		Week 2	12-MAY-2001	Restaurant	4	8	1
		Week 3	12-MAY-2001	Bar	1	30	3
			22-MAY-2001	No Exposure			

^a Subject Classification: M-NS=Male, Non-Smoker; F-NS=Female, Non-Smoker.

^b 1=Light, 2=Moderate, and 3=Heavy.

Listing 16.5-15
Non-Smoker Diaries by Subject
(Page 13 of 16)

Subject Number	Subject Classification ^a	Timepoint	Date	Location	Number of Hours Exposed	Number of Cigarettes Smoked by Others	Intensity ^b
121	M-NS	Week 6	09-JUN-2001	Wedding reception	4	4	1
			10-JUN-2001	Wedding reception	1	1	1
122	M-NS	Week 1	10-MAY-2001	No Exposure			
		Week 2	13-MAY-2001	House	1	2	1
		Week 3	19-MAY-2001	House	2	3	1
			19-MAY-2001	Restaurant	1	5	2
			20-MAY-2001	House	1	2	1
		Week 6	12-JUN-2001	House	1	2	1
				House	1	2	1
123	M-NS	Week 1	08-MAY-2001	Merrimac cafe	1	6	2
			09-JUN-2001	Cafe	5	1	2
			10-JUN-2001	Cafe	1	4	2
		Week 2	15-MAY-2001	Merrimac restaurant	1	5	2
		Week 6	12-JUN-2001	Cafe	1	4-5	2
				Cafe	1	4-5	2
124	M-NS	Week 1	09-MAY-2001	Outside	3	8	1
		Week 2	09-MAY-2001	Outside	1	7	2
			12-MAY-2001	Outside	1	1	2
		Week 3	19-MAY-2001	Outside	2	2	2
		Week 6	22-MAY-2001	Car	1	1	1
			10-JUN-2001	Outside	1	1	1
125	M-NS	Week 1	09-MAY-2001	No Exposure			
		Week 2	14-MAY-2001	No Exposure			
		Week 3	23-MAY-2001	No Exposure			
		Week 6	18-JUN-2001	No Exposure			
126	M-NS	Week 1	09-MAY-2001	No Exposure			
		Week 2	15-MAY-2001	No Exposure			
		Week 3	23-MAY-2001	No Exposure			
		Week 6	12-JUN-2001	No Exposure			

^a Subject Classification: M-NS=Male, Non-Smoker; F-NS=Female, Non-Smoker.

^b 1=Light, 2=Moderate, and 3=Heavy.

Listing 16.5-15
Non-Smoker Diaries by Subject
(Page 14 of 16)

Subject Number	Subject Classification ^a	Timepoint	Date	Location	Number of Hours Exposed	Number of Cigarettes Smoked by Others	Intensity ^b
127	M-NS	Week 1	11-MAY-2001	No Exposure			
		Week 2	14-MAY-2001	No Exposure			
		Week 3	23-MAY-2001	No Exposure			
		Week 6	11-JUN-2001	No Exposure			
128	M-NS	Week 1	07-MAY-2001	Home	3	5	1
			07-MAY-2001	Capital square	1	1	1
			08-MAY-2001	Capital square	1	2	1
			08-MAY-2001	Home	3	5	1
		Week 2	09-MAY-2001	Home	1	1	1
			09-MAY-2001	Capital square	1	1	1
			11-MAY-2001	Home	1	1	1
			12-MAY-2001	Home	3	3	1
		Week 3	14-MAY-2001	Home	1	1	1
			19-MAY-2001	Home	2	2	1
			20-MAY-2001	Home	2	2	1
		Week 6	10-JUN-2001	Home	2	2	1
			11-JUN-2001	Home	3	3	1
129	M-NS	Week 1	10-MAY-2001	No Exposure			
		Week 2	14-MAY-2001	No Exposure			
		Week 3	22-MAY-2001	No Exposure			
		Week 6	11-JUN-2001	No Exposure			
130	M-NS	Week 1	07-MAY-2001	Restaurant	1	2	1
		Week 2	15-MAY-2001	No Exposure			
		Week 3	23-MAY-2001	No Exposure			
		Week 6	13-JUN-2001	No Exposure			
131	M-NS	Week 1	07-MAY-2001	Breakroom	2	15	1
			07-MAY-2001	Breakroom	1	10	2
			08-MAY-2001	Breakroom	2	18	1
			09-MAY-2001	Breakroom	1	20	2
			09-MAY-2001	Breakroom	1	10	1

^a Subject Classification: M-NS=Male, Non-Smoker; F-NS=Female, Non-Smoker.

^b 1=Light, 2=Moderate, and 3=Heavy.

Listing 16.5-15
Non-Smoker Diaries by Subject
(Page 15 of 16)

Subject Number	Subject Classification ^a	Timepoint	Date	Location	Number of Hours Exposed	Number of Cigarettes Smoked by Others	Intensity ^b
131	M-NS	Week 2	14-MAY-2001	No Exposure			
		Week 3	21-MAY-2001	No Exposure			
		Week 6	12-JUN-2001	No Exposure			
132	M-NS	Week 1	10-MAY-2001	No Exposure			
		Week 2	18-MAY-2001	No Exposure			
		Week 3	21-MAY-2001	Work	1	2	1
133	M-NS	Week 1	10-MAY-2001	No Exposure			
		Week 2	16-MAY-2001	No Exposure			
		Week 3	23-MAY-2001	No Exposure			
		Week 6	14-JUN-2001	No Exposure			
134	M-NS	Week 1	13-MAY-2001	Bar	1	15	2
			14-MAY-2001	Bar	1	10	2
			16-MAY-2001	House	1	8	3
		Week 2	24-MAY-2001	House	1	8	2
		Week 3	30-MAY-2001	No Exposure			
		Week 6	16-JUN-2001	Car	1	3	1
			16-JUN-2001	House	1	2	1
			17-JUN-2001	Porch	1	2	1
135	M-NS	Week 1	08-MAY-2001	Bar	2	4	1
			09-MAY-2001	Bar/restaurant	1	8	2
			09-MAY-2001	Bar/restaurant	2	3	1
		Week 2	14-MAY-2001	Restaurant	1	2	1
			16-MAY-2001	House	1	1	1
		Week 3	23-MAY-2001	No Exposure			
		Week 6	09-JUN-2001	House	2	12	1
			10-JUN-2001	Bar	2	40	3
			11-JUN-2001	House	2	20	2
500	F-NS	Week 1	06-MAY-2001	Bar	5	69	1

^a Subject Classification: M-NS=Male, Non-Smoker; F-NS=Female, Non-Smoker.

^b 1=Light, 2=Moderate, and 3=Heavy.

Listing 16.5-15
Non-Smoker Diaries by Subject
(Page 16 of 16)

Subject Number	Subject Classification ^a	Timepoint	Date	Location	Number of Hours Exposed	Number of Cigarettes Smoked by Others	Intensity ^b
500	F-NS	Week 2	11-MAY-2001	Bar	3	155	1
			11-MAY-2001	Bar	4	305	2
			12-MAY-2001	Car	1	1	1
			12-MAY-2001	Bar	1	50	1
		Week 3	19-MAY-2001	Bar	9	88	1
			20-MAY-2001	Bar	6	66	1
		Week 6	08-JUN-2001	Bar	1	30	2
			08-JUN-2001	Bar	5	69	1
			10-JUN-2001	Bar	5	18	1
501	F-NS	Week 1	10-MAY-2001	No Exposure			
		Week 2	12-MAY-2001	Restaurant bathroom	3 min	Not Reported	3
		Week 3	23-MAY-2001	No Exposure			
		Week 6	14-JUN-2001	No Exposure			

^a Subject Classification: M-NS—Male, Non-Smoker, F-NS—Female, Non-Smoker.

^b 1=Light, 2=Moderate, and 3=Heavy.

Listing 16.5-16
Urine Drug Screen by Subject
(Page 1 of 12)

Subject Number	Subject Classification ^a	Timepoint	Result
001	F-S	Screening Enrollment	Neg Neg
002	F-S	Screening Enrollment	Neg Neg
003	F-S	Screening Enrollment	Neg Neg
004	F-S	Screening Enrollment	Neg Neg
005	F-S	Screening Enrollment	Neg Neg
006	F-S	Screening Enrollment	Neg Neg
007	F-S	Screening Enrollment	Neg Neg
008	F-S	Screening Enrollment	Neg Neg
009	F-S	Screening Enrollment	Neg Neg
010	F-S	Screening Enrollment	Neg Neg
011	F-S	Screening Enrollment	Neg Neg
012	F-S	Screening Enrollment	Neg Neg

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-16
Urine Drug Screen by Subject
(Page 2 of 12)

Subject Number	Subject Classification ^a	Timepoint	Result
013	F-S	Screening Enrollment	Neg Neg
014	F-S	Screening Enrollment	Neg Norpropoxyphene (Confirmed) Propoxyphene metab.(Confirmed)
015	F-S	Screening Enrollment	Neg Neg
016	F-S	Screening Enrollment	Neg Neg
017	F-S	Screening Enrollment	Neg Neg
018	F-S	Screening Enrollment	Neg Neg
019	F-S	Screening Enrollment	Neg Neg
020	F-S	Screening Enrollment	Neg Neg
021	F-S	Screening Enrollment	Neg Neg
022	F-S	Screening Enrollment	Neg Neg
023	F-S	Screening Enrollment	Neg Neg

^a Subject Classification: M-NS-Male, Non-Smoker; M-S-Male, Smoker; F-NS-Female, Non-Smoker; F-S-Female, Smoker.

Listing 16.5-16
Urine Drug Screen by Subject
(Page 3 of 12)

Subject Number	Subject Classification ^a	Timepoint	Result
024	F-S	Screening Enrollment	Neg Neg
025	F-S	Screening Enrollment	Neg Neg
026	F-S	Screening Enrollment	Neg Neg
027	F-S	Screening Enrollment	Neg Neg
028	F-S	Screening Enrollment	Neg Neg
029	F-S	Screening Enrollment	Neg Neg
030	F-S	Screening Enrollment	Neg Neg
031	F-S	Screening Enrollment	Neg Neg
032	F-S	Screening Enrollment	Neg Neg
033	F-S	Screening Enrollment	Neg Neg
034	F-S	Screening Enrollment	Neg Neg
035	F-S	Screening Enrollment	Neg Neg

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-16
Urine Drug Screen by Subject
(Page 4 of 12)

Subject Number	Subject Classification ^a	Timepoint	Result
036	M-S	Screening Enrollment	Neg Neg
037	M-S	Screening Enrollment	Neg Neg
038	M-S	Screening Enrollment	Neg Neg
039	M-S	Screening Enrollment	Neg Neg
040	M-S	Screening Enrollment	Neg Neg
041	M-S	Screening Enrollment	Neg Neg
042	M-S	Screening Enrollment	Neg Neg
043	M-S	Screening Enrollment	Neg Neg
044	M-S	Screening Enrollment	Neg Neg
045	M-S	Screening Enrollment	Neg Neg
046	M-S	Screening Enrollment	Neg Neg
047	M-S	Screening Enrollment	Neg Neg

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630033

Draft 1: 24 July 2002

Page 14678 of 15132

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-16
Urine Drug Screen by Subject
(Page 5 of 12)

Subject Number	Subject Classification ^a	Timepoint	Result
048	M-S	Screening Enrollment	Neg Neg
049	M-S	Screening Enrollment	Neg Neg
050	M-S	Screening Enrollment	Neg Neg
051	M-S	Screening Enrollment	Neg THC (Confirmed)
052	M-S	Screening Enrollment	Neg Neg
053	M-S	Screening Enrollment	Neg THC (Confirmed)
054	M-S	Screening Enrollment	Neg Neg
055	M-S	Screening Enrollment	Neg Neg
056	M-S	Screening Enrollment	Neg Neg
057	M-S	Screening Enrollment	Neg Neg
058	M-S	Screening Enrollment	Neg Neg
059	M-S	Screening Enrollment	Neg Neg

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker

PM3006630034

Listing 16.5-16
Urine Drug Screen by Subject
(Page 6 of 12)

Subject Number	Subject Classification ^a	Timepoint	Result
060	M-S	Screening Enrollment	Neg Neg
061	M-S	Screening Enrollment	Neg Neg
062	M-S	Screening Enrollment	Neg Neg
063	M-S	Screening Enrollment	Neg Neg
065	M-S	Screening Enrollment	Neg Neg
066	M-S	Screening Enrollment	6-MAM not present Morphine (Confirmed) 6-MAM not present Codeine (Confirmed) Methadone (Confirmed) Morphine (Confirmed)
067	M-S	Screening Enrollment	Neg Neg
068	M-S	Screening Enrollment	Neg 6-MAM not present Codeine (Confirmed) Codeine metab.(Confirmed) Morphine (Confirmed)
069	M-S	Screening Enrollment	Propoxyphene (Confirmed) Norpropoxyphene (Confirmed) Propoxyphene metab.(Confirmed) Neg

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-16
Urine Drug Screen by Subject
(Page 7 of 12)

Subject Number	Subject Classification ^a	Timepoint	Result
071	F-NS	Screening Enrollment	Neg Neg
072	F-NS	Screening Enrollment	Neg Neg
073	F-NS	Screening Enrollment	Neg Neg
074	F-NS	Screening Enrollment	Neg Neg
075	F-NS	Screening Enrollment	Neg Neg
076	F-NS	Screening Enrollment	Neg Neg
077	F-NS	Screening Enrollment	Neg Neg
078	F-NS	Screening Enrollment	Neg Neg
079	F-NS	Screening Enrollment	Neg Neg
080	F-NS	Screening Enrollment	Neg Neg
081	F-NS	Screening Enrollment	Neg Neg
082	F-NS	Screening Enrollment	Neg Neg

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-16
Urine Drug Screen by Subject
(Page 8 of 12)

Subject Number	Subject Classification ^a	Timepoint	Result
083	F-NS	Screening Enrollment	Neg Neg
084	F-NS	Screening Enrollment	Neg Neg
085	F-NS	Screening Enrollment	Neg Neg
086	F-NS	Screening Enrollment	Neg Neg
087	F-NS	Screening Enrollment	Neg Neg
088	F-NS	Screening Enrollment	Neg Neg
089	F-NS	Screening Enrollment	Neg Neg
090	F-NS	Screening Enrollment	Neg Neg
091	F-NS	Screening Enrollment	Neg Neg
092	F-NS	Screening Enrollment	Neg Neg
093	F-NS	Screening Enrollment	Neg Neg
094	F-NS	Screening Enrollment	Neg Neg

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-16
Urine Drug Screen by Subject
(Page 9 of 12)

Subject Number	Subject Classification ^a	Timepoint	Result
095	F-NS	Screening Enrollment	Neg Neg
096	F-NS	Screening Enrollment	Neg Neg
097	F-NS	Screening Enrollment	Neg Neg
098	F-NS	Screening Enrollment	Neg Neg
099	F-NS	Screening Enrollment	Neg Neg
100	F-NS	Screening Enrollment	Neg Neg
101	F-NS	Screening Enrollment	Neg Neg
102	F-NS	Screening Enrollment	Neg Neg
103	F-NS	Screening Enrollment	Neg Neg
104	M-NS	Screening Enrollment	Neg Neg
105	M-NS	Screening Enrollment	Neg Neg
106	M-NS	Screening Enrollment	Neg Neg

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS= Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-16
Urine Drug Screen by Subject
(Page 10 of 12)

Subject Number	Subject Classification ^a	Timepoint	Result
107	M-NS	Screening Enrollment	Neg Neg
108	M-NS	Screening Enrollment	Neg Neg
109	M-NS	Screening Enrollment	Neg Neg
110	M-NS	Screening Enrollment	Neg Neg
111	M-NS	Screening Enrollment	Neg Neg
112	M-NS	Screening Enrollment	Neg Neg
113	M-NS	Screening Enrollment	Neg Neg
114	M-NS	Screening Enrollment	Neg Neg
115	M-NS	Screening Enrollment	Neg Neg
116	M-NS	Screening Enrollment	Neg Neg
117	M-NS	Screening Enrollment	Neg Neg
118	M-NS	Screening Enrollment	Neg Neg

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630039

Draft 1: 24 July 2002

Page 14684 of 15132

Listing 16.5-16
Urine Drug Screen by Subject
(Page 11 of 12)

Subject Number	Subject Classification ^a	Timepoint	Result
119	M-NS	Screening Enrollment	Neg Neg
120	M-NS	Screening Enrollment	Neg Neg
121	M-NS	Screening Enrollment	Neg Neg
122	M-NS	Screening Enrollment	Neg Neg
123	M-NS	Screening Enrollment	Neg Neg
124	M-NS	Screening Enrollment	Neg Neg
125	M-NS	Screening Enrollment	Neg Neg
126	M-NS	Screening Enrollment	Neg Neg
127	M-NS	Screening Enrollment	Neg Neg
128	M-NS	Screening Enrollment	Neg Neg
129	M-NS	Screening Enrollment	Neg Neg
130	M-NS	Screening Enrollment	Neg Neg

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-16
Urine Drug Screen by Subject
(Page 12 of 12)

Subject Number	Subject Classification ^a	Timepoint	Result
131	M-NS	Screening Enrollment	Neg Neg
132	M-NS	Screening Enrollment	Neg Neg
133	M-NS	Screening Enrollment	Neg Neg
134	M-NS	Screening Enrollment	Neg Neg
135	M-NS	Screening Enrollment	Neg Neg
500	F-NS	Screening Enrollment	Neg Neg
501	F-NS	Screening Enrollment	Neg Neg
502	F-S	Screening Enrollment	Neg Neg
503	F-S	Screening Enrollment	Neg Neg
504	F-S	Screening Enrollment	Neg Neg
505	F-NS	Screening Enrollment	Neg Neg
506	F-S	Screening Enrollment	Neg Neg

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630041

Draft 1: 24 July 2002

Page 14686 of 15132

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-17
Screening 12-Lead ECGs by Subject
(Page 1 of 8)

Subject Number	Subject Classification*	Ventricular Heart Rate (beats/min)	Interpretation	Finding
001	F-S	75	Normal	
002	F-S	90	Normal	
003	F-S	63	Normal	
004	F-S	89	Normal	
005	F-S	71	Normal	
006	F-S	62	Normal	
007	F-S	59	Normal	
008	F-S	75	Normal	
009	F-S	56	Abnormal (NCS)	
010	F-S	46	Normal	
011	F-S	64	Normal	
012	F-S	76	Normal	
013	F-S	67	Normal	
014	F-S	64	Normal	
015	F-S	60	Normal	
016	F-S	68	Normal	
017	F-S	76	Normal	
018	F-S	60	Normal	
019	F-S	65	Normal	

* Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630042

Listing 16.5-17
Screening 12-Lead ECGs by Subject
(Page 2 of 8)

Subject Number	Subject Classification ^a	Ventricular Heart Rate (beats/min)	Interpretation	Finding
020	F-S	83	Abnormal (NCS)	
021	F-S	58	Normal	
022	F-S	59	Normal	
023	F-S	74	Abnormal (NCS)	
024	F-S	69	Normal	
025	F-S	81	Normal	
026	F-S	58	Normal	
027	F-S	71	Abnormal (NCS)	
028	F-S	80	Abnormal (NCS)	
029	F-S	65	Abnormal (NCS)	
030	F-S	69	Normal	
031	F-S	68	Normal	
032	F-S	74	Normal	
033	F-S	66	Abnormal (NCS)	
034	F-S	55	Normal	
035	F-S	67	Normal	
036	M-S	60	Normal	
037	M-S	54	Abnormal (NCS)	
038	M-S	76	Normal	

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630043

Listing 16.3-17
Screening 12-Lead ECGs by Subject
(Page 3 of 8)

Subject Number	Subject Classification ^a	Ventricular Heart Rate (beats/min)	Interpretation	Finding
039	M-S	79	Abnormal (NCS)	
040	M-S	53	Normal	
041	M-S	60	Abnormal (NCS)	
042	M-S	72	Normal	
043	M-S	55	Normal	
044	M-S	54	Abnormal (NCS)	
045	M-S	80	Abnormal (NCS)	
046	M-S	60	Normal	
047	M-S	58	Normal	
048	M-S	58	Abnormal (NCS)	
049	M-S	53	Normal	
050	M-S	54	Abnormal (NCS)	Repeated ECG WNL
051	M-S	54	Normal	
052	M-S	54	Abnormal (NCS)	
053	M-S	66	Normal	
054	M-S	54	Abnormal (NCS)	
055	M-S	69	Normal	
056	M-S	50	Abnormal (NCS)	
057	M-S	77	Normal	

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-17
Screening 12 Lead ECGs by Subject
(Page 4 of 8)

Subject Number	Subject Classification*	Ventricular Heart Rate (beats/min)	Interpretation	Finding
058	M-S	55	Abnormal (NCS)	
059	M-S	63	Normal	
060	M-S	66	Normal	
061	M-S	70	Normal	
062	M-S	69	Normal	
063	M-S	93	Normal	
065	M-S	60	Abnormal (NCS)	
066	M-S	63	Normal	
067	M-S	62	Normal	
068	M-S	71	Normal	
069	M-S	57	Abnormal (NCS)	
071	F-NS	81	Normal	
072	F-NS	78	Normal	
073	F-NS	70	Normal	
074	F-NS	81	Normal	
075	F-NS	73	Normal	
076	F-NS	68	Normal	
077	F-NS	75	Normal	
078	F-NS	63	Normal	

* Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630045

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-17
Screening 12-Lead ECGs by Subject
(Page 5 of 8)

Subject Number	Subject Classification ^a	Ventricular Heart Rate (beats/min)	Interpretation	Finding
079	F-NS	69	Normal	
080	F-NS	68	Normal	
081	F-NS	61	Normal	
082	F-NS	55	Normal	
083	F-NS	75	Normal	
084	F-NS	71	Normal	
085	F-NS	70	Normal	
086	F-NS	81	Normal	
087	F-NS	69	Normal	
088	F-NS	74	Normal	
089	F-NS	61	Abnormal (NCS)	
090	F-NS	65	Normal	
091	F-NS	68	Normal	
092	F-NS	70	Normal	
093	F-NS	76	Normal	
094	F-NS	75	Abnormal (NCS)	
095	F-NS	60	Normal	
096	F-NS	56	Normal	
097	F-NS	59	Normal	

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630046

Draft 1: 24 July 2002

Page 14691 of 15132

Listing 16.5-17
Screening 12-Lead ECGs by Subject
(Page 6 of 8)

Subject Number	Subject Classification ^a	Ventricular Heart Rate (beats/min)	Interpretation	Finding
098	F-NS	60	Normal	
099	F-NS	64	Normal	
100	F-NS	73	Normal	
101	F-NS	69	Normal	
102	F-NS	65	Normal	
103	F-NS	71	Normal	
104	M-NS	58	Normal	
105	M-NS	59	Abnormal (NCS)	
106	M-NS	42	Abnormal (NCS)	
107	M-NS	57	Normal	
108	M-NS	59	Normal	
109	M-NS	80	Normal	
110	M-NS	63	Normal	
111	M-NS	58	Normal	
112	M-NS	56	Normal	
113	M-NS	46	Normal	
114	M-NS	57	Normal	
115	M-NS	75	Normal	
116	M-NS	60	Normal	

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

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Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-17
Screening 12-Lead ECGs by Subject
(Page 7 of 8)

Subject Number	Subject Classification ^a	Ventricular Heart Rate (beats/min)	Interpretation	Finding
117	M-NS	64	Normal	
118	M-NS	60	Normal	
119	M-NS	72	Normal	
120	M-NS	55	Normal	
121	M-NS	90	Normal	
122	M-NS	50	Normal	
123	M-NS	50	Abnormal (NCS)	
124	M-NS	43	Normal	
125	M-NS	70	Normal	
126	M-NS	70	Abnormal (NCS)	
127	M-NS	64	Normal	
128	M-NS	55	Normal	
129	M-NS	57	Abnormal (NCS)	
130	M-NS	48	Abnormal (NCS)	
131	M-NS	57	Normal	
132	M-NS	54	Normal	
133	M-NS	64	Abnormal (NCS)	
134	M-NS	54	Normal	
135	M-NS	57	Normal	

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630048

Listing 16.5-17
Screening 12-Lead ECGs by Subject
(Page 8 of 8)

Subject Number	Subject Classification ^a	Ventricular Heart Rate (beats/min)	Interpretation	Finding
500	F-NS	65	Abnormal (NCS)	
501	F-NS	53	Abnormal (NCS)	
502	F-S	57	Normal	
503	F-S	56	Normal	
504	F-S	55	Normal	
505	F-NS	56	Normal	
506	F-S	72	Normal	

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-18
Screening Lung Function Tests by Subject
(Page 1 of 8)

Subject Number	Subject Classification ^a	FVC (%)	FEV1 (%)
001	F-S	119	81
002	F-S	76	77
003	F-S	106	109
004	F-S	124	110
005	F-S	112	112
006	F-S	106	76
007	F-S	87	97
008	F-S	100	98
009	F-S	127	86
010	F-S	96	96
011	F-S	102	86
012	F-S	104	92
013	F-S	116	94
014	F-S	134	133
015	F-S	106	80
016	F-S	93	84
017	F-S	98	97
018	F-S	124	112
019	F-S	87	76

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630050

Listing 16.5-18
Screening Lung Function Tests by Subject
(Page 2 of 8)

Subject Number	Subject Classification ^a	FVC (%)	FEV1 (%)
020	F-S	114	92
021	F-S	87	87
022	F-S	102	98
023	F-S	123	103
024	F-S	114	105
025	F-S	97	93
026	F-S	89	84
027	F-S	111	105
028	F-S	131	131
029	F-S	96	84
030	F-S	96	91
031	F-S	115	101
032	F-S	103	79
033	F-S	107	75
034	F-S	93	89
035	F-S	96	91
036	M-S	103	99
037	M-S	98	93
038	M-S	109	96

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630051

Listing 16.5-18
Screening Lung Function Tests by Subject
(Page 3 of 8)

Subject Number	Subject Classification ^a	FVC (%)	FEV1 (%)
039	M-S	158	79
040	M-S	92	84
041	M-S	133	127
042	M-S	96	106
043	M-S	100	95
044	M-S	116	119
045	M-S	95	86
046	M-S	92	82
047	M-S	87	75
048	M-S	105	97
049	M-S	133	96
050	M-S	133	83
051	M-S	117	113
052	M-S	113	106
053	M S	99	100
054	M-S	93	90
055	M-S	99	96
056	M-S	81	76
057	M-S	102	96

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630052

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-18
Screening Lung Function Tests by Subject
(Page 4 of 8)

Subject Number	Subject Classification ^a	FVC (%)	FEV1 (%)
058	M-S	104	106
059	M-S	98	85
060	M-S	103	78
061	M-S	105	90
062	M-S	109	103
063	M-S	75	76
065	M-S	89	95
066	M-S	107	116
067	M-S	116	114
068	M-S	122	115
069	M-S	99	87
071	F-NS	118	118
072	F-NS	136	117
073	F-NS	126	115
074	F-NS	107	109
075	F-NS	96	81
076	F-NS	113	109
077	F-NS	115	106
078	F-NS	101	105

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630053

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-18
Screening Lung Function Tests by Subject
(Page 5 of 8)

Subject Number	Subject Classification ^a	FVC (%)	FEV1 (%)
079	F-NS	125	96
080	F-NS	114	111
081	F-NS	121	128
082	F-NS	104	89
083	F-NS	112	100
084	F-NS	98	80
085	F-NS	107	104
086	F-NS	101	82
087	F-NS	111	95
088	F-NS	117	100
089	F-NS	101	92
090	F-NS	100	99
091	F-NS	90	83
092	F-NS	115	100
093	F-NS	110	102
094	F-NS	106	109
095	F-NS	119	108
096	F-NS	132	116
097	F-NS	106	91

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630054

Listing 16.5-18
Screening Lung Function Tests by Subject
(Page 6 of 8)

Subject Number	Subject Classification ^a	FVC (%)	FEV1 (%)
098	F-NS	128	118
099	F-NS	81	88
100	F-NS	92	102
101	F-NS	98	96
102	F-NS	104	97
103	F-NS	81	76
104	M-NS	82	85
105	M-NS	104	90
106	M-NS	105	93
107	M-NS	128	107
108	M-NS	114	110
109	M-NS	81	91
110	M-NS	106	105
111	M-NS	110	84
112	M-NS	111	101
113	M-NS	132	125
114	M-NS	93	89
115	M-NS	106	94
116	M-NS	87	77

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS= Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-18
Screening Lung Function Tests by Subject
(Page 7 of 8)

Subject Number	Subject Classification ^a	FVC (%)	FEV1 (%)
117	M-NS	109	108
118	M-NS	105	92
119	M-NS	108	84
120	M-NS	130	113
121	M-NS	108	85
122	M-NS	102	109
123	M-NS	119	101
124	M-NS	99	95
125	M-NS	100	78
126	M-NS	94	95
127	M-NS	96	82
128	M-NS	113	99
129	M-NS	105	79
130	M-NS	110	86
131	M-NS	133	120
132	M-NS	83	88
133	M-NS	105	105
134	M-NS	101	111
135	M-NS	75	80

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-18
Screening Lung Function Tests by Subject
(Page 8 of 8)

Subject Number	Subject Classification ^a	FVC (%)	FEV1 (%)
500	F-NS	105	97
501	F-NS	129	116
502	F-S	119	100
503	F-S	114	104
504	F-S	109	87
505	F-NS	120	114
506	F-S	122	116

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-19
Vital Signs by Subject
(Page 1 of 27)

Subject Number	Subject Classification ^a	Timepoint	Blood Pressure		Pulse (beats/min)	Respiration (breaths/min)	Oral Temperature (°C)
			Systolic (mmHg)	Diastolic (mmHg)			
001	F-S	Screening	151	76	82	12	36.7
		Enrollment	152	80	94	16	37.1
		Week 1	153	84	90	16	37.7
		Week 2	147	81	87	16	36.7
		Week 3	161	99	81	16	36.4
		Week 6	126	73	89	12	36.3
002	F-S	Screening	146	81	89	12	37.3
		Enrollment	156	89	97	16	37.4
		Week 1	151	77	86	16	37.4
		Week 2	142	82	89	16	37.2
		Week 3	145	86	82	16	37.3
		Week 6	122	76	91	12	36.6
003	F-S	Screening	117	66	62	12	36.6
		Enrollment	127	70	68	16	36.9
		Week 1	146	75	86	16	37.1
		Week 2	103	63	80	16	37.3
		Week 3	132	74	80	16	37.4
		Week 6	114	75	86	16	36.6
004	F-S	Screening	112	82	94	16	36.9
		Enrollment	112	84	114	16	37.1
		Week 1	106	75	105	12	37.4
		Week 2	111	79	90	12	36.2
		Week 3	103	71	78	20	36.5
		Week 6	116	81	84	12	37.1
005	F-S	Screening	144	71	73	16	36.3
		Enrollment	137	81	79	16	36.4
		Week 1	137	79	81	16	36.2
		Week 2	117	62	86	16	36.9
		Week 3	95	60	64	16	36.8
		Week 6	121	77	69	12	36.6

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-19
Vital Signs by Subject
(Page 2 of 27)

Subject Number	Subject Classification ^a	Timepoint	Blood Pressure		Pulse (beats/min)	Respiration (breaths/min)	Oral Temperature (°C)
			Systolic (mmHg)	Diastolic (mmHg)			
006	F-S	Screening	116	69	68	20	37.0
		Enrollment	114	76	74	16	36.7
		Week 1	123	77	72	16	36.6
		Week 2	105	69	68	12	36.1
		Week 3	116	71	55	16	36.2
		Week 6	106	71	86	16	36.7
007	F-S	Screening	99	66	64	16	36.2
		Enrollment	99	67	72	12	36.4
		Week 1	107	62	76	16	36.4
		Week 2	101	59	80	20	36.9
		Week 3	110	75	66	20	36.5
		Week 6	112	73	68	Unknown	36.4
008	F-S	Screening	112	79	90	16	37.6
		Enrollment	126	76	80	16	37.2
		Week 1	109	73	73	16	36.6
		Week 2	114	70	70	25	37.0
		Week 3	112	74	76	16	37.6
		Week 6	95	69	87	16	36.7
009	F-S	Screening	129	69	61	16	36.6
		Enrollment	135	69	63	16	36.6
		Week 1	142	66	64	12	36.8
		Week 2	121	57	70	16	36.4
		Week 3	128	59	71	16	36.7
		Week 6	120	61	73	16	36.3
010	F-S	Screening	101	56	52	12	36.7
		Enrollment	107	61	49	16	36.1
		Week 1	114	73	79	16	36.1
		Week 2	111	65	59	16	37.1
011	F-S	Screening	148	78	65	16	36.4
		Enrollment	129	75	84	16	36.7
		Week 1	142	91	90	16	36.4
		Week 2	152	89	66	12	36.4
		Week 3	152	74	80	20	36.3
		Week 6	144	81	90	16	36.7

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.3-19
Vital Signs by Subject
(Page 3 of 27)

Subject Number	Subject Classification ^a	Timepoint	Blood Pressure		Pulse (beats/min)	Respiration (breaths/min)	Oral Temperature (°C)
			Systolic (mmHg)	Diastolic (mmHg)			
012	F-S	Screening	121	71	76	16	37.3
		Enrollment	117	74	81	16	37.3
		Week 1	132	81	86	16	36.9
		Week 2	112	60	85	16	36.7
		Week 3	126	76	85	20	36.8
		Week 6	108	63	77	16	36.7
013	F-S	Screening	116	76	80	16	36.8
		Enrollment	110	69	76	16	36.4
		Week 1	108	74	82	12	36.5
		Week 2	109	69	79	12	36.2
		Week 3	100	65	76	16	36.1
		Week 6	103	71	82	16	36.2
014	F-S	Screening	110	72	67	12	37.1
		Enrollment	111	67	78	12	36.6
		Week 1	110	71	72	16	36.9
		Week 2	127	63	76	16	36.7
		Week 3	110	76	76	20	36.3
		Week 6	106	68	80	16	36.8
015	F-S	Screening	116	83	83	16	37.3
		Enrollment	116	83	82	12	36.9
		Week 1	114	76	93	16	37.1
		Week 2	114	74	68	12	36.6
		Week 3	111	73	73	12	36.8
		Week 6	115	77	89	20	37.5
016	F-S	Screening	111	60	74	12	37.0
		Enrollment	117	66	85	16	37.2
		Week 1	109	68	80	16	36.8
		Week 2	114	62	78	16	37.2
		Week 3	135	64	65	16	36.9
		Week 6	116	66	74	16	37.3

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-19
Vital Signs by Subject
(Page 4 of 27)

Subject Number	Subject Classification ^a	Timepoint	Blood Pressure		Pulse (beats/min)	Respiration (breaths/min)	Oral Temperature (°C)
			Systolic (mmHg)	Diastolic (mmHg)			
017	F-S	Screening	126	63	85	12	37.1
		Enrollment	112	64	87	16	37.0
		Week 1	100	59	81	16	37.4
		Week 2	113	70	82	20	36.5
		Week 3	105	55	62	12	36.8
		Week 6	110	63	73	16	36.6
018	F-S	Screening	91	53	62	16	36.7
		Enrollment	99	68	77	16	36.2
		Week 1	97	63	74	16	36.7
		Week 2	95	62	70	12	36.4
		Week 3	93	60	67	16	36.2
		Week 6	96	64	78	16	36.6
019	F-S	Screening	129	61	73	16	36.4
		Enrollment	145	75	78	16	36.8
		Week 1	143	69	79	16	37.2
		Week 2	132	70	86	20	36.9
		Week 3	93	49	87	16	36.8
		Week 6	137	68	88	16	37.0
020	F-S	Screening	100	62	86	16	37.2
		Enrollment	120	73	86	12	36.9
		Week 1	117	69	82	16	37.6
		Week 2	104	64	87	12	37.2
		Week 3	109	62	96	16	36.8
		Week 6	126	69	81	16	37.2
021	F-S	Screening	91	59	63	12	36.8
		Enrollment	104	68	67	12	36.2
		Week 1	110	65	70	20	36.2
		Week 2	107	66	70	16	36.3
		Week 3	111	65	73	20	36.5
		Week 6	103	68	78	16	36.1

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-19
Vital Signs by Subject
(Page 5 of 27)

Subject Number	Subject Classification ^a	Timepoint	Blood Pressure		Pulse (beats/min)	Respiration (breaths/min)	Oral Temperature (°C)
			Systolic (mmHg)	Diastolic (mmHg)			
022	F-S	Screening	120	72	75	16	36.8
		Enrollment	131	82	78	12	36.8
		Week 1	128	85	76	16	37.1
		Week 2	108	75	73	16	37.1
		Week 3	113	75	65	16	36.9
		Week 6	117	75	80	12	36.6
023	F-S	Screening	106	63	77	12	37.0
		Enrollment	102	61	83	12	36.4
		Week 1	97	58	70	16	36.3
		Week 2	104	63	88	16	37.4
		Week 3	107	62	76	16	36.5
		Week 6	117	71	85	12	36.7
024	F-S	Screening	106	76	84	16	37.1
		Enrollment	115	78	95	16	36.5
		Week 1	105	78	72	16	36.6
		Week 2	111	78	78	12	36.2
		Week 3	110	79	93	20	36.6
		Week 6	105	80	75	16	36.3
025	F-S	Screening	157	88	95	16	36.9
		Enrollment	155	93	101	12	36.8
		Week 1	137	84	117	16	37.1
		Week 2	143	86	88	16	36.7
		Week 3	113	81	97	16	36.6
		Week 6	143	88	93	16	36.3
026	F-S	Screening	106	68	61	16	36.2
		Enrollment	120	79	65	16	36.7
		Week 1	121	74	64	16	36.2
		Week 2	114	65	76	16	36.8
		Week 3	103	58	79	16	36.8
		Week 6	111	65	62	12	36.4

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-19
Vital Signs by Subject
(Page 6 of 27)

Subject Number	Subject Classification ^a	Timepoint	Blood Pressure		Pulse (beats/min)	Respiration (breaths/min)	Oral Temperature (°C)
			Systolic (mmHg)	Diastolic (mmHg)			
027	F-S	Screening	99	54	77	16	36.4
		Enrollment	101	58	97	16	37.2
		Week 1	100	56	98	16	36.8
		Week 2	90	53	93	16	36.7
		Week 3	111	50	82	20	36.7
		Week 6	108	60	86	16	37.7
028	F-S	Screening	103	59	78	16	36.2
		Enrollment	123	68	83	16	37.1
		Week 1	113	67	89	16	36.6
		Week 2	114	59	78	20	36.3
		Week 3	110	64	84	16	37.3
		Week 6	112	61	83	12	36.4
029	F-S	Screening	93	65	64	16	36.6
		Enrollment	112	65	68	16	36.8
		Week 1	111	72	74	16	36.6
		Week 2	102	56	68	16	36.4
		Week 3	109	60	72	16	36.3
		Week 6	106	61	74	16	36.6
030	F-S	Screening	122	69	77	16	37.0
		Enrollment	126	77	77	16	36.6
		Week 1	138	81	85	16	36.9
		Week 2	120	74	79	16	36.8
		Week 3	131	84	78	20	36.7
		Week 6	131	85	80	12	37.1
031	F-S	Screening	135	75	73	16	36.8
		Enrollment	113	71	70	16	36.8
		Week 1	106	67	76	16	36.9
		Week 2	128	66	69	12	36.7
		Week 3	123	62	78	16	37.1
		Week 6	116	63	80	16	36.9

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-19
Vital Signs by Subject
(Page 7 of 27)

Subject Number	Subject Classification ^a	Timepoint	Blood Pressure		Pulse (beats/min)	Respiration (breaths/min)	Oral Temperature (°C)
			Systolic (mmHg)	Diastolic (mmHg)			
032	F-S	Screening	113	66	70	16	37.7
		Enrollment	144	69	79	16	36.3
		Week 1	132	65	79	16	36.2
		Week 2	120	70	86	16	36.7
		Week 3	132	64	86	20	36.3
		Week 6	122	67	67	12	36.7
033	F-S	Screening	111	75	80	16	36.4
		Enrollment	115	71	88	16	37.1
		Week 1	121	80	71	16	36.2
		Week 2	112	84	79	16	36.9
		Week 3	104	71	80	16	37.1
		Week 6	107	78	61	16	36.1
034	F-S	Screening	101	67	58	16	36.3
		Enrollment	103	63	66	16	36.9
		Week 1	110	72	69	16	36.4
		Week 2	115	77	71	16	36.4
		Week 3	110	73	67	16	36.4
		Week 6	104	70	80	12	36.3
035	F-S	Screening	107	68	74	16	36.2
		Enrollment	117	77	86	16	37.0
		Week 1	104	61	75	16	36.6
		Week 2	123	67	70	16	36.2
		Week 3	120	80	75	16	36.2
		Week 6	112	75	75	16	36.2
036	M-S	Screening	104	70	60	12	36.3
		Enrollment	116	67	62	16	36.4
		Week 1	128	78	68	16	37.3
		Week 2	108	73	74	16	37.5
		Week 3	111	60	58	16	36.8
		Week 6	116	78	59	12	36.3

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-19
Vital Signs by Subject
(Page 8 of 27)

Subject Number	Subject Classification ^a	Timepoint	Blood Pressure		Pulse (beats/min)	Respiration (breaths/min)	Oral Temperature (°C)
			Systolic (mmHg)	Diastolic (mmHg)			
037	M-S	Screening	110	66	60	16	36.5
		Enrollment	116	65	74	12	36.1
		Week 1	112	70	62	12	36.2
		Week 2	108	68	63	16	36.1
		Week 3	110	65	56	16	36.4
		Week 6	112	68	77	16	36.4
038	M-S	Screening	139	67	71	12	36.1
		Enrollment	154	89	81	16	36.9
		Week 1	134	70	67	16	36.5
		Week 2	134	69	64	16	36.2
		Week 3	134	77	74	20	36.3
		Week 6	144	68	72	16	36.3
039	M-S	Screening	151	104	83	16	36.9
		Enrollment	110	84	82	16	36.1
		Week 1	139	86	86	12	36.2
		Week 2	136	93	82	16	36.4
		Week 3	126	85	75	12	37.0
		Week 6	114	93	83	12	36.1
040	M-S	Screening	137	76	59	12	37.0
		Enrollment	134	75	66	12	37.3
		Week 1	113	76	62	12	36.7
		Week 2	133	78	56	16	36.8
		Week 3	129	68	64	16	36.9
		Week 6	133	78	56	12	36.2
041	M-S	Screening	100	65	76	12	37.0
		Enrollment	104	69	88	16	37.1
		Week 1	103	76	97	16	36.8
		Week 2	97	65	87	20	36.3
		Week 3	115	72	82	16	36.3
		Week 6	95	64	81	12	36.2

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-19
Vital Signs by Subject
(Page 9 of 27)

Subject Number	Subject Classification ^a	Timepoint	Blood Pressure		Pulse (beats/min)	Respiration (breaths/min)	Oral Temperature (°C)
			Systolic (mmHg)	Diastolic (mmHg)			
042	M-S	Screening	167	88	67	16	37.3
		Enrollment	168	88	72	16	36.8
		Week 1	167	84	69	16	37.0
		Week 2	163	77	81	16	36.7
		Week 3	167	81	76	20	36.9
		Week 6	168	93	89	16	36.4
043	M-S	Screening	123	71	64	12	36.9
		Enrollment	115	88	82	16	36.1
		Week 1	126	81	85	12	36.7
		Week 2	115	69	78	16	36.2
		Week 3	121	63	66	16	36.1
		Week 6	114	72	64	16	36.1
044	M-S	Screening	126	63	69	16	37.0
		Enrollment	121	69	50	16	36.7
		Week 1	117	72	81	16	36.2
		Week 2	116	67	79	16	37.3
		Week 3	122	69	67	12	36.2
		Week 6	121	64	71	12	36.7
045	M-S	Screening	143	79	112	16	36.3
		Enrollment	147	90	83	16	36.0
		Week 1	152	82	93	12	37.1
		Week 2	143	89	86	16	36.7
		Week 3	137	81	72	20	36.2
		Week 6	139	80	83	16	37.1
046	M-S	Screening	96	67	65	16	36.3
		Enrollment	100	66	75	16	36.4
		Week 1	117	81	74	16	36.6
		Week 2	114	75	69	20	36.2
		Week 3	110	86	74	20	36.2
		Week 6	101	74	80	12	36.3

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-19
Vital Signs by Subject
(Page 10 of 27)

Subject Number	Subject Classification ^a	Timepoint	Blood Pressure		Pulse (beats/min)	Respiration (breaths/min)	Oral Temperature (°C)
			Systolic (mmHg)	Diastolic (mmHg)			
047	M-S	Screening	108	58	59	16	36.9
		Enrollment	115	73	86	16	36.8
		Week 1	109	63	86	12	37.4
		Week 2	109	59	82	12	36.8
		Week 3	107	66	80	16	36.7
		Week 6	113	60	83	16	37.0
048	M-S	Screening	127	68	60	16	36.8
		Enrollment	145	74	63	16	37.3
		Week 1	123	66	87	12	36.8
		Week 2	143	66	83	16	37.0
		Week 3	131	59	56	16	37.2
		Week 6	142	72	74	16	36.8
049	M-S	Screening	139	80	55	16	36.1
		Enrollment	137	83	70	16	36.3
		Week 1	137	79	62	16	36.1
		Week 2	129	83	61	16	36.1
		Week 3	138	82	72	16	36.1
		Week 6	136	84	60	12	36.1
050	M-S	Screening	115	79	64	16	36.7
		Enrollment	116	81	59	16	36.8
		Week 1	131	74	65	12	36.3
		Week 2	123	80	71	16	36.8
		Week 3	129	76	68	16	36.2
		Week 6	132	86	70	16	36.2
051	M-S	Screening	126	71	73	16	36.5
		Enrollment	127	65	72	16	37.1
052	M-S	Screening	98	59	60	12	36.7
		Enrollment	108	68	74	16	36.9
		Week 1	102	69	67	16	36.1
		Week 2	106	66	66	16	36.1
		Week 3	101	61	81	16	36.7
		Week 6	110	71	68	16	36.7

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-19
Vital Signs by Subject
(Page 11 of 27)

Subject Number	Subject Classification ^a	Timepoint	Blood Pressure		Pulse (beats/min)	Respiration (breaths/min)	Oral Temperature (°C)
			Systolic (mmHg)	Diastolic (mmHg)			
053	M-S	Screening	102	65	72	12	36.4
		Enrollment	131	83	78	16	36.4
054	M-S	Screening	133	65	53	12	36.9
		Enrollment	132	72	59	16	36.3
		Week 1	135	63	69	16	37.4
		Week 2	123	57	60	12	36.4
		Week 3	136	60	64	16	36.9
		Week 6	139	62	68	12	37.2
055	M-S	Screening	128	78	77	16	36.2
		Enrollment	133	87	86	16	36.3
		Week 1	133	83	91	16	36.6
		Week 2	133	75	76	16	36.6
		Week 3	127	74	77	16	36.4
		Week 6	133	80	77	16	36.7
056	M-S	Screening	114	73	57	16	36.1
		Enrollment	110	68	67	16	36.4
		Week 1	93	66	108	16	35.9
		Week 2	114	74	67	16	36.3
		Week 3	110	71	68	16	36.2
		Week 6	113	74	84	12	36.1
057	M-S	Screening	137	78	80	16	36.5
		Enrollment	134	75	86	16	36.3
		Week 1	137	76	93	20	36.8
		Week 2	122	72	89	16	36.8
		Week 3	135	69	86	20	36.1
		Week 6	128	68	77	16	36.1
058	M-S	Screening	136	67	60	20	36.3
		Enrollment	128	72	65	16	36.1
		Week 1	127	72	63	16	37.1
		Week 2	133	69	62	12	36.7
		Week 3	131	80	59	20	36.1
		Week 6	113	71	63	16	36.7

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-19
Vital Signs by Subject
(Page 12 of 27)

Subject Number	Subject Classification ^a	Timepoint	Blood Pressure		Pulse (beats/min)	Respiration (breaths/min)	Oral Temperature (°C)
			Systolic (mmHg)	Diastolic (mmHg)			
059	M-S	Screening	115	74	85	16	36.8
		Enrollment	107	70	71	16	36.4
		Week 1	115	83	74	16	37.1
		Week 2	115	78	68	12	36.8
		Week 3	126	69	68	12	37.0
		Week 6	122	75	80	16	36.6
060	M-S	Screening	126	68	75	16	36.4
		Enrollment	134	72	101	16	36.2
		Week 1	155	83	100	16	36.6
		Week 2	137	73	86	16	36.7
		Week 3	144	75	80	16	36.4
		Week 6	121	73	100	16	36.6
061	M-S	Screening	113	71	78	16	36.2
		Enrollment	131	78	74	16	36.3
		Week 1	136	82	74	16	36.7
		Week 2	113	71	67	16	36.2
		Week 3	117	73	75	12	37.1
		Week 6	98	71	96	16	36.4
062	M-S	Screening	136	84	73	16	37.0
		Enrollment	138	83	66	16	36.3
		Week 1	152	95	64	16	36.4
		Week 2	143	85	63	16	36.7
		Week 3	138	86	74	16	36.7
		Week 6	155	96	77	16	36.8
063	M-S	Screening	120	76	100	16	36.4
		Enrollment	116	74	103	16	36.6
		Week 1	110	80	89	16	36.6
		Week 2	105	69	91	16	36.5
		Week 3	111	71	94	20	36.4
		Week 6	120	67	105	16	36.7

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-19
Vital Signs by Subject
(Page 13 of 27)

Subject Number	Subject Classification ^a	Timepoint	Blood Pressure		Pulse (beats/min)	Respiration (breaths/min)	Oral Temperature (°C)
			Systolic (mmHg)	Diastolic (mmHg)			
065	M-S	Screening	145	70	68	12	36.7
		Enrollment	138	63	74	16	36.8
		Week 1	132	64	74	16	36.4
		Week 2	134	60	57	20	36.4
		Week 3	121	69	77	16	36.6
		Week 6	128	67	66	20	36.9
066	M-S	Screening	131	84	76	16	37.1
		Enrollment	102	69	68	16	37.1
067	M-S	Screening	113	66	66	12	36.9
		Enrollment	145	86	69	16	37.7
		Week 1	151	71	83	16	36.4
		Week 2	144	74	57	12	36.1
		Week 3	144	76	61	16	36.5
		Week 6	139	75	86	16	36.8
068	M-S	Screening	129	81	93	16	36.9
		Enrollment	144	91	74	16	36.6
		Week 1	153	88	97	16	36.1
		Week 2	153	90	68	12	36.1
		Week 3	148	87	86	16	36.6
		Week 6	157	83	74	16	36.7
069	M-S	Screening	120	63	84	16	36.8
		Enrollment	121	72	76	12	36.9
		Week 1	115	63	60	16	37.7
		Week 2	112	67	74	16	37.1
		Week 3	117	67	75	16	36.8
		Week 6	115	77	88	16	37.4
071	F-NS	Screening	139	81	86	16	37.2
		Enrollment	121	68	84	16	36.5
		Week 1	133	79	78	16	36.9
		Week 2	123	75	86	16	36.4
		Week 3	120	73	80	16	36.8
		Week 6	129	73	76	12	37.0

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-19
Vital Signs by Subject
(Page 14 of 27)

Subject Number	Subject Classification ^a	Timepoint	Blood Pressure		Pulse (beats/min)	Respiration (breaths/min)	Oral Temperature (°C)
			Systolic (mmHg)	Diastolic (mmHg)			
072	F-NS	Screening	112	78	67	12	36.9
		Enrollment	95	67	80	20	36.3
		Week 1	100	64	90	16	36.8
		Week 2	104	75	74	16	36.7
		Week 3	95	63	64	16	36.9
		Week 6	99	69	80	20	36.6
073	F-NS	Screening	115	74	72	16	37.6
		Enrollment	109	68	70	16	36.1
		Week 1	113	70	77	16	36.8
		Week 2	111	72	65	20	36.7
		Week 3	107	64	72	20	36.5
		Week 6	106	69	67	16	36.4
074	F-NS	Screening	143	76	84	12	37.0
		Enrollment	133	76	98	16	36.9
		Week 1	135	76	81	16	37.1
		Week 2	133	67	86	16	36.9
		Week 3	134	64	81	16	36.6
		Week 6	134	73	80	16	36.5
075	F-NS	Screening	108	61	66	16	36.2
		Enrollment	105	61	68	16	36.9
		Week 1	110	63	70	16	37.1
		Week 2	105	65	80	16	36.1
		Week 3	100	63	66	16	36.1
		Week 6	111	72	67	12	36.3
076	F-NS	Screening	148	76	61	16	36.7
		Enrollment	142	80	66	16	36.2
		Week 1	153	82	59	16	36.2
		Week 2	131	72	66	12	36.6
		Week 3	134	74	64	12	36.2
		Week 6	134	75	73	16	36.6

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-19
Vital Signs by Subject
(Page 15 of 27)

Subject Number	Subject Classification ^a	Timepoint	Blood Pressure		Pulse (beats/min)	Respiration (breaths/min)	Oral Temperature (°C)
			Systolic (mmHg)	Diastolic (mmHg)			
077	F-NS	Screening	120	75	80	12	36.6
		Enrollment	109	74	82	12	36.7
		Week 1	109	69	89	16	36.6
		Week 2	121	70	103	16	36.2
		Week 3	104	67	91	20	36.4
		Week 6	106	73	86	16	36.2
078	F-NS	Screening	110	61	72	16	36.4
		Enrollment	95	62	80	12	36.9
		Week 1	97	58	75	16	37.1
		Week 2	103	67	76	16	36.7
		Week 3	101	59	72	16	37.5
		Week 6	100	62	72	12	37.2
079	F-NS	Screening	99	50	69	12	36.8
		Enrollment	93	56	69	12	36.7
		Week 1	103	56	72	16	37.0
		Week 2	97	51	75	16	36.9
		Week 3	98	64	90	20	37.0
		Week 6	105	58	79	12	36.6
080	F-NS	Screening	161	89	72	16	36.9
		Enrollment	146	88	74	16	36.7
		Week 1	113	73	80	16	36.7
		Week 2	120	72	68	16	36.2
		Week 3	129	82	68	12	36.9
		Week 6	117	82	68	12	36.7
081	F-NS	Screening	111	61	68	16	36.3
		Enrollment	100	57	61	12	36.9
		Week 1	99	50	73	16	37.1
		Week 2	104	59	71	16	36.8
		Week 3	103	55	65	16	37.1
		Week 6	95	60	81	12	37.2

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-19
Vital Signs by Subject
(Page 16 of 27)

Subject Number	Subject Classification ^a	Timepoint	Blood Pressure		Pulse (beats/min)	Respiration (breaths/min)	Oral Temperature (°C)
			Systolic (mmHg)	Diastolic (mmHg)			
082	F-NS	Screening	113	75	60	16	36.4
		Enrollment	107	73	64	16	36.6
		Week 1	122	78	62	16	37.1
		Week 2	131	79	54	16	36.1
		Week 3	129	88	57	16	35.7
		Week 6	123	77	82	20	36.8
083	F-NS	Screening	107	66	69	16	36.8
		Enrollment	104	67	66	16	36.2
		Week 1	107	71	79	12	36.8
		Week 2	113	69	68	12	36.4
		Week 3	115	67	75	20	36.1
		Week 6	110	74	70	12	36.2
084	F-NS	Screening	115	62	76	16	36.9
		Enrollment	137	79	74	16	36.8
		Week 1	126	67	80	16	36.9
		Week 2	131	74	78	12	36.1
		Week 3	113	65	77	20	37.0
		Week 6	133	70	86	12	36.6
085	F-NS	Screening	139	77	70	16	37.0
		Enrollment	116	72	77	16	36.3
		Week 1	126	67	66	12	37.1
		Week 2	131	63	82	16	37.4
		Week 3	129	75	69	16	36.8
		Week 6	122	69	76	16	37.2
086	F-NS	Screening	131	74	91	16	37.6
		Enrollment	114	67	109	16	36.2
		Week 1	123	79	101	16	37.0
		Week 2	121	72	86	12	36.8
		Week 3	122	72	90	20	36.7
		Week 6	134	85	95	16	36.7

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-19
Vital Signs by Subject
(Page 17 of 27)

Subject Number	Subject Classification ^a	Timepoint	Blood Pressure		Pulse (beats/min)	Respiration (breaths/min)	Oral Temperature (°C)
			Systolic (mmHg)	Diastolic (mmHg)			
087	F-NS	Screening	114	63	76	12	37.2
		Enrollment	108	67	75	16	36.6
		Week 1	133	68	71	16	37.1
		Week 2	121	65	70	12	37.3
		Week 3	116	63	70	12	36.9
		Week 6	112	58	72	12	36.6
088	F-NS	Screening	154	86	78	12	37.4
		Enrollment	134	88	75	16	36.9
		Week 1	145	87	74	16	37.3
		Week 2	147	91	70	16	37.1
		Week 3	135	81	80	16	37.2
		Week 6	143	92	72	16	36.6
089	F-NS	Screening	93	64	55	16	36.7
		Enrollment	88	51	69	16	36.4
		Week 1	94	56	59	12	36.6
		Week 2	87	54	71	12	36.4
		Week 3	90	49	52	16	36.4
		Week 6	103	62	66	12	36.2
090	F-NS	Screening	174	83	85	16	37.1
		Enrollment	149	76	88	16	36.7
		Week 1	156	64	73	16	36.8
		Week 2	156	71	72	12	36.4
		Week 3	158	59	84	16	36.7
		Week 6	165	69	78	16	36.3
091	F-NS	Screening	142	81	73	16	37.1
		Enrollment	165	94	78	16	36.3
		Week 1	165	83	76	16	37.3
		Week 2	157	88	70	12	37.2
		Week 3	176	80	71	12	37.3
		Week 6	153	91	73	16	36.4

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-19
Vital Signs by Subject
(Page 18 of 27)

Subject Number	Subject Classification ^a	Timepoint	Blood Pressure		Pulse (beats/min)	Respiration (breaths/min)	Oral Temperature (°C)
			Systolic (mmHg)	Diastolic (mmHg)			
092	F-NS	Screening	123	72	66	16	36.8
		Enrollment	127	84	85	16	35.9
		Week 1	123	68	77	16	36.4
		Week 2	121	71	80	12	36.6
		Week 3	113	73	80	20	36.2
		Week 6	117	84	70	Unknown	35.6
093	F-NS	Screening	103	63	83	16	36.9
		Enrollment	102	72	88	16	36.6
		Week 1	104	65	84	12	37.4
		Week 2	103	61	85	16	37.4
		Week 3	113	61	90	12	36.6
		Week 6	99	64	80	16	36.9
094	F-NS	Screening	116	79	76	16	36.3
		Enrollment	131	75	103	16	36.7
		Week 1	110	74	76	16	36.3
		Week 2	108	64	89	12	37.4
		Week 3	112	73	86	16	36.9
		Week 6	110	66	90	16	37.8
095	F-NS	Screening	151	87	81	16	36.3
		Enrollment	127	84	74	16	36.4
		Week 1	147	81	84	12	36.1
		Week 2	121	76	75	12	36.6
		Week 3	134	77	71	16	36.2
		Week 6	148	90	74	12	36.1
096	F-NS	Screening	110	65	65	16	37.3
		Enrollment	110	64	62	16	37.3
		Week 1	113	60	77	16	37.3
		Week 2	115	74	62	16	36.5
		Week 3	137	69	61	20	36.7
		Week 6	106	72	67	16	37.4

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-19
Vital Signs by Subject
(Page 19 of 27)

Subject Number	Subject Classification ^a	Timepoint	Blood Pressure		Pulse (beats/min)	Respiration (breaths/min)	Oral Temperature (°C)
			Systolic (mmHg)	Diastolic (mmHg)			
097	F-NS	Screening	131	85	67	16	36.7
		Enrollment	123	90	80	16	36.7
		Week 1	142	91	74	16	36.2
		Week 2	128	78	74	12	37.0
		Week 3	117	81	68	12	36.8
		Week 6	128	88	85	16	36.7
098	F-NS	Screening	113	73	73	16	36.7
		Enrollment	104	77	73	12	36.9
		Week 1	112	71	65	12	36.2
		Week 2	113	78	70	16	37.1
		Week 3	114	72	68	12	36.7
		Week 6	108	75	60	16	36.1
099	F-NS	Screening	116	70	68	16	37.4
		Enrollment	114	66	64	16	36.4
		Week 1	123	71	71	12	37.0
		Week 2	134	75	74	16	36.2
		Week 3	121	77	66	20	36.4
		Week 6	117	70	76	16	35.9
100	F-NS	Screening	137	74	85	16	36.3
		Enrollment	104	78	81	16	35.9
		Week 1	117	79	74	12	36.2
		Week 2	114	72	66	16	36.1
		Week 3	110	75	72	12	36.2
		Week 6	122	75	72	12	36.3
101	F-NS	Screening	112	62	66	12	36.2
		Enrollment	112	71	59	16	36.1
		Week 1	126	67	72	16	36.2
		Week 2	122	78	81	16	37.3
		Week 3	123	73	68	16	35.6
		Week 6	109	63	74	20	36.5

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-19
Vital Signs by Subject
(Page 20 of 27)

Subject Number	Subject Classification ^a	Timepoint	Blood Pressure		Pulse (beats/min)	Respiration (breaths/min)	Oral Temperature (°C)
			Systolic (mmHg)	Diastolic (mmHg)			
102	F-NS	Screening	112	67	70	12	36.6
		Enrollment	107	63	78	16	36.1
		Week 1	113	76	103	16	36.3
		Week 2	106	61	70	12	36.9
		Week 3	106	63	67	16	36.8
		Week 6	123	67	79	16	36.3
103	F-NS	Screening	134	75	79	16	36.5
		Enrollment	113	78	70	16	36.1
		Week 1	121	67	75	12	37.5
		Week 2	115	70	73	16	36.6
		Week 3	122	60	68	16	36.5
		Week 6	121	71	82	20	36.5
104	M-NS	Screening	100	61	58	12	36.5
		Enrollment	112	65	59	12	36.3
		Week 1	115	64	54	12	36.8
		Week 2	106	61	63	16	36.6
		Week 3	111	61	62	16	36.2
		Week 6	115	62	64	16	36.4
105	M-NS	Screening	128	81	53	12	36.2
		Enrollment	122	80	50	16	36.2
		Week 1	136	77	58	12	36.2
		Week 2	143	79	64	16	36.2
		Week 3	126	70	51	16	36.0
		Week 6	144	88	67	12	35.7
106	M-NS	Screening	144	75	49	12	36.2
		Enrollment	109	61	44	12	35.9
		Week 1	113	68	42	16	35.9
		Week 2	122	70	58	12	36.6
		Week 3	112	65	41	16	36.8
		Week 6	113	69	39	16	36.2

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-19
Vital Signs by Subject
(Page 21 of 27)

Subject Number	Subject Classification ^a	Timepoint	Blood Pressure		Pulse (beats/min)	Respiration (breaths/min)	Oral Temperature (°C)
			Systolic (mmHg)	Diastolic (mmHg)			
107	M-NS	Screening	136	68	66	12	36.9
		Enrollment	133	72	66	12	36.1
		Week 1	133	70	73	16	36.7
		Week 2	131	62	64	12	36.8
		Week 3	134	64	60	16	ND
		Week 6	137	74	60	20	36.2
108	M-NS	Screening	133	74	59	16	37.4
		Enrollment	123	79	57	12	37.2
		Week 1	108	75	82	16	37.7
		Week 2	135	82	76	16	37.1
		Week 3	131	78	93	16	37.7
		Week 6	120	79	86	16	37.5
109	M-NS	Screening	121	77	82	12	36.9
		Enrollment	106	70	61	16	36.2
		Week 1	116	71	65	12	36.9
		Week 2	107	68	68	16	37.2
		Week 3	107	63	63	20	36.5
		Week 6	114	74	62	16	36.5
110	M-NS	Screening	122	66	61	12	36.7
		Enrollment	128	76	57	16	36.4
		Week 1	139	83	66	12	37.0
		Week 2	137	86	61	12	36.6
		Week 3	123	65	63	16	37.1
		Week 6	133	75	67	16	36.3
111	M-NS	Screening	121	66	67	16	36.9
		Enrollment	116	69	66	16	36.4
		Week 1	113	79	68	16	37.3
		Week 2	108	65	61	16	36.8
		Week 3	113	71	66	16	36.7
		Week 6	113	72	66	16	36.4

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-19
Vital Signs by Subject
(Page 22 of 27)

Subject Number	Subject Classification ^a	Timepoint	Blood Pressure		Pulse (beats/min)	Respiration (breaths/min)	Oral Temperature (°C)
			Systolic (mmHg)	Diastolic (mmHg)			
112	M-NS	Screening	126	83	57	12	36.3
		Enrollment	107	76	67	16	36.1
		Week 1	104	75	66	16	36.0
		Week 2	123	88	57	16	36.2
		Week 3	116	81	65	16	36.4
		Week 6	117	88	67	12	36.6
113	M-NS	Screening	113	72	49	12	36.4
		Enrollment	104	79	55	16	36.3
		Week 1	109	77	47	12	36.3
		Week 2	112	68	51	16	36.8
114	M-NS	Screening	121	64	67	16	36.7
		Enrollment	115	80	59	16	36.8
		Week 1	117	80	68	16	36.7
		Week 2	117	72	65	16	36.4
		Week 3	111	69	67	16	36.7
		Week 6	123	78	58	12	36.4
115	M-NS	Screening	138	59	81	16	36.1
		Enrollment	132	75	98	16	36.2
		Week 1	115	63	74	16	36.2
		Week 2	114	58	70	16	36.1
		Week 3	113	60	72	20	36.1
		Week 6	135	74	78	16	36.1
116	M-NS	Screening	111	73	66	16	36.6
		Enrollment	123	65	69	12	36.2
		Week 1	123	68	74	16	36.2
		Week 2	138	72	80	16	36.3
		Week 3	109	60	61	16	36.4
		Week 6	142	78	76	20	36.6
117	M-NS	Screening	152	86	84	12	37.1
		Enrollment	128	78	64	16	37.6
		Week 1	135	83	68	12	36.6
		Week 2	134	81	69	16	36.8
		Week 3	116	78	54	16	37.1
		Week 6	121	72	64	12	36.0

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630079

Listing 16.5-19
Vital Signs by Subject
(Page 23 of 27)

Subject Number	Subject Classification ^a	Timepoint	Blood Pressure		Pulse (beats/min)	Respiration (breaths/min)	Oral Temperature (°C)
			Systolic (mmHg)	Diastolic (mmHg)			
118	M-NS	Screening	117	75	64	12	36.2
		Enrollment	131	91	70	16	36.4
		Week 1	121	78	72	12	36.7
		Week 2	Unknown	Unknown	Unknown	Unknown	Unknown
		Week 3	116	67	69	16	36.9
		Week 6	Unknown	Unknown	Unknown	Unknown	Unknown
119	M-NS	Screening	122	78	74	12	36.8
		Enrollment	134	76	73	16	36.1
		Week 1	156	72	76	16	36.5
		Week 2	149	71	76	16	36.2
		Week 3	129	59	76	16	36.5
		Week 6	139	75	77	16	36.6
120	M-NS	Screening	121	75	70	16	36.8
		Enrollment	128	90	62	16	36.1
		Week 1	115	86	60	16	36.8
		Week 2	139	78	69	16	36.4
		Week 3	126	80	66	20	36.9
		Week 6	126	76	76	16	36.4
121	M-NS	Screening	111	56	88	16	35.8
		Enrollment	117	66	103	16	36.2
		Week 1	100	61	98	12	36.2
		Week 2	133	80	86	16	36.7
		Week 3	126	70	94	16	36.8
		Week 6	103	64	87	16	37.3
122	M-NS	Screening	111	67	53	12	36.4
		Enrollment	105	63	63	16	36.3
		Week 1	121	66	58	12	36.1
		Week 2	116	63	50	16	36.2
		Week 3	112	56	50	16	36.3
		Week 6	109	64	56	12	36.1

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-19
Vital Signs by Subject
(Page 24 of 27)

Subject Number	Subject Classification ^a	Timepoint	Blood Pressure		Pulse (beats/min)	Respiration (breaths/min)	Oral Temperature (°C)
			Systolic (mmHg)	Diastolic (mmHg)			
123	M-NS	Screening	155	84	55	12	36.5
		Enrollment	144	80	48	12	36.1
		Week 1	134	66	48	16	36.3
		Week 2	136	76	47	12	35.6
		Week 3	109	72	64	16	36.4
		Week 6	132	80	57	20	36.7
124	M-NS	Screening	131	61	55	16	36.3
		Enrollment	137	70	66	12	36.4
		Week 1	127	61	61	12	36.9
		Week 2	136	65	66	16	36.9
		Week 3	132	63	53	20	36.0
		Week 6	126	69	64	16	36.6
125	M-NS	Screening	128	76	76	16	36.8
		Enrollment	122	80	70	16	36.7
		Week 1	136	78	86	12	36.7
		Week 2	123	71	72	16	36.3
		Week 3	137	70	76	20	37.0
		Week 6	132	85	67	16	36.9
126	M-NS	Screening	163	95	72	16	36.4
		Enrollment	157	78	73	16	36.2
		Week 1	157	84	75	12	36.1
		Week 2	139	82	60	12	36.8
		Week 3	161	90	60	16	36.0
		Week 6	138	84	64	16	36.4
127	M-NS	Screening	105	79	87	16	36.7
		Enrollment	113	68	77	16	36.3
		Week 1	117	69	68	16	36.7
		Week 2	114	70	67	16	36.3
		Week 3	129	57	71	16	37.0
		Week 6	122	70	76	12	36.8

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-19
Vital Signs by Subject
(Page 25 of 27)

Subject Number	Subject Classification ^a	Timepoint	Blood Pressure		Pulse (beats/min)	Respiration (breaths/min)	Oral Temperature (°C)
			Systolic (mmHg)	Diastolic (mmHg)			
128	M-NS	Screening	121	77	65	16	36.3
		Enrollment	114	65	65	16	36.1
		Week 1	121	73	80	12	36.9
		Week 2	112	72	63	16	36.7
		Week 3	134	79	63	16	36.9
		Week 6	135	84	78	16	37.2
129	M-NS	Screening	126	61	54	16	36.6
		Enrollment	132	78	68	16	36.4
		Week 1	115	61	60	12	36.3
		Week 2	128	66	62	16	36.2
		Week 3	123	65	59	16	36.1
		Week 6	117	72	57	16	36.5
130	M-NS	Screening	129	72	58	12	36.6
		Enrollment	128	72	47	16	36.3
		Week 1	113	71	42	12	36.4
		Week 2	120	72	45	16	37.2
		Week 3	129	75	47	20	36.1
		Week 6	127	76	42	16	36.4
131	M-NS	Screening	123	88	67	12	36.8
		Enrollment	131	89	74	16	36.1
		Week 1	131	97	84	12	37.1
		Week 2	144	94	82	16	36.7
		Week 3	129	90	85	12	36.8
		Week 6	139	89	76	16	36.4
132	M-NS	Screening	121	79	68	16	36.3
		Enrollment	128	88	68	16	36.3
		Week 1	134	73	66	12	36.1
		Week 2	131	79	66	12	36.2
		Week 3	138	70	70	16	36.1
		Week 6	139	81	72	16	36.2

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-19
Vital Signs by Subject
(Page 26 of 27)

Subject Number	Subject Classification ^a	Timepoint	Blood Pressure		Pulse (beats/min)	Respiration (breaths/min)	Oral Temperature (°C)
			Systolic (mmHg)	Diastolic (mmHg)			
133	M-NS	Screening	98	60	72	16	36.7
		Enrollment	106	68	90	16	36.1
		Week 1	106	64	73	12	36.7
		Week 2	109	60	76	12	36.5
		Week 3	109	62	68	16	36.8
		Week 6	107	55	80	16	36.4
134	M-NS	Screening	122	58	59	12	36.7
		Enrollment	131	63	82	16	36.2
		Week 1	109	70	66	12	36.9
		Week 2	107	63	67	12	36.9
		Week 3	129	74	89	16	36.7
		Week 6	117	62	62	16	36.8
135	M-NS	Screening	121	69	63	12	36.8
		Enrollment	122	75	71	12	36.3
		Week 1	115	76	70	16	36.2
		Week 2	117	69	54	16	36.4
		Week 3	115	68	61	16	36.4
		Week 6	129	84	73	16	37.0
500	F-NS	Screening	142	78	94	16	37.4
		Enrollment	134	76	66	16	36.7
		Week 1	133	90	80	16	37.0
		Week 2	139	66	84	16	36.4
		Week 3	139	78	66	12	36.9
		Week 6	129	83	80	16	36.6
501	F-NS	Screening	116	65	61	12	36.9
		Enrollment	106	80	74	16	36.2
		Week 1	121	70	70	16	36.4
		Week 2	121	67	62	16	36.4
		Week 3	128	67	61	16	36.1
		Week 6	121	68	62	12	36.3

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-19
Vital Signs by Subject
(Page 27 of 27)

Subject Number	Subject Classification ^a	Timepoint	Blood Pressure		Pulse (beats/min)	Respiration (breaths/min)	Oral Temperature (°C)
			Systolic (mmHg)	Diastolic (mmHg)			
502	F-S	Screening	114	60	87	12	36.9
		Enrollment	105	61	83	16	37.1
		Week 1	106	58	79	16	36.4
		Week 2	102	54	76	16	37.0
		Week 3	108	58	77	16	36.5
		Week 6	108	67	93	12	37.2
503	F-S	Screening	126	68	62	12	37.1
		Enrollment	116	73	70	16	36.4
		Week 1	127	71	83	16	37.3
		Week 2	116	65	67	16	37.0
		Week 3	123	58	73	16	36.8
		Week 6	126	68	78	12	37.2
504	F-S	Screening	111	61	57	16	36.8
		Enrollment	94	58	62	16	36.6
		Week 1	93	55	76	12	37.1
		Week 2	104	50	72	16	36.9
		Week 3	99	60	68	20	36.6
		Week 6	88	52	60	16	36.9
505	F-NS	Screening	147	85	57	16	36.2
		Enrollment	142	90	62	16	36.6
		Week 1	142	86	64	16	36.3
		Week 2	136	81	54	16	36.3
		Week 3	126	80	55	20	36.7
		Week 6	146	83	60	16	36.4
506	F-S	Screening	110	59	78	16	36.7
		Enrollment	129	59	88	16	37.4
		Week 1	113	72	97	16	37.2
		Week 2	110	69	82	12	37.1
		Week 3	111	67	95	16	37.8
		Week 6	114	67	79	12	37.1

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-20
Pregnancy Test Results by Subject (Females Only)
(Page 1 of 15)

Subject Number	Subject Classification ^a	Timepoint	Result
001	F-S	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 3	Negative
002	F-S	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
003	F-S	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
004	F-S	Screening	NA
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
005	F-S	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
006	F-S	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative

^a Subject Classification: F-NS= Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-20
Pregnancy Test Results by Subject (Females Only)
(Page 2 of 15)

Subject Number	Subject Classification ^a	Timepoint	Result
007	F-S	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
008	F-S	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	NA
		Week 3	Negative
		Week 6	Negative
009	F-S	Screening	NA
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
010	F-S	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
011	F-S	Screening	NA
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
012	F-S	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative

^a Subject Classification: F-NS= Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-20
Pregnancy Test Results by Subject (Females Only)
(Page 3 of 15)

Subject Number	Subject Classification ^a	Timepoint	Result
013	F-S	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
014	F-S	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
015	F-S	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
016	F-S	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
017	F-S	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative

^a Subject Classification: F-NS= Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-20
Pregnancy Test Results by Subject (Females Only)
(Page 4 of 15)

Subject Number	Subject Classification ^a	Timepoint	Result
018	F-S	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
019	F-S	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
020	F-S	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
021	F-S	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
022	F-S	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative

^a Subject Classification: F-NS= Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-20
Pregnancy Test Results by Subject (Females Only)
(Page 5 of 15)

Subject Number	Subject Classification ^a	Timepoint	Result
023	F-S	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
024	F-S	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
025	F-S	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
026	F-S	Screening	NA
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
027	F-S	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative

^a Subject Classification: F-NS= Female, Non-Smoker; F-S= Female, Smoker.

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Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-20
Pregnancy Test Results by Subject (Females Only)
(Page 6 of 15)

Subject Number	Subject Classification ^a	Timepoint	Result
028	F-S	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
029	F-S	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
030	F-S	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
031	F-S	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
032	F-S	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative

^a Subject Classification: F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630090

Draft 1: 24 July 2002

Page 14735 of 15132

Listing 16.5-20
Pregnancy Test Results by Subject (Females Only)
(Page 7 of 15)

Subject Number	Subject Classification ^a	Timepoint	Result
033	F-S	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
034	F-S	Week 6	Negative
		Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
035	F-S	Week 3	Negative
		Week 6	Negative
		Screening	Negative
		Enrollment	Negative
		Week 1	Negative
071	F-NS	Week 2	Negative
		Week 3	Negative
		Week 6	Negative
		Screening	Negative
		Enrollment	Negative
072	F-NS	Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
		Screening	Negative

^a Subject Classification: F-NS= Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-20
Pregnancy Test Results by Subject (Females Only)
(Page 8 of 15)

Subject Number	Subject Classification ^a	Timepoint	Result
073	F-NS	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
074	F-NS	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
075	F-NS	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
076	F-NS	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
077	F-NS	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative

^a Subject Classification: F-NS= Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-20
Pregnancy Test Results by Subject (Females Only)
(Page 9 of 15)

Subject Number	Subject Classification ^a	Timepoint	Result
078	F-NS	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
079	F-NS	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
080	F-NS	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
081	F-NS	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
082	F-NS	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative

^a Subject Classification: F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-20
Pregnancy Test Results by Subject (Females Only)
(Page 10 of 15)

Subject Number	Subject Classification ^a	Timepoint	Result
083	F-NS	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
084	F-NS	Screening	NA
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
085	F-NS	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
086	F-NS	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
087	F-NS	Screening	NA
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative

^a Subject Classification: F-NS= Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-20
Pregnancy Test Results by Subject (Females Only)
(Page 11 of 15)

Subject Number	Subject Classification ^a	Timepoint	Result
088	F-NS	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
089	F-NS	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
090	F-NS	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
091	F-NS	Screening	NA
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
092	F-NS	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative

^a Subject Classification: F-NS= Female, Non-Smoker; F-S= Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-20
Pregnancy Test Results by Subject (Females Only)
(Page 12 of 15)

Subject Number	Subject Classification ^a	Timepoint	Result
093	F-NS	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
094	F-NS	Week 6	Negative
		Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
095	F-NS	Week 3	Negative
		Week 6	Negative
		Screening	Negative
		Enrollment	Negative
		Week 1	Negative
096	F-NS	Week 2	Negative
		Week 3	Negative
		Week 6	Negative
		Screening	Negative
		Enrollment	Negative
097	F-NS	Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
		Screening	Negative

^a Subject Classification: F-NS- Female, Non-Smoker; F-S- Female, Smoker.

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Listing 16.5-20
Pregnancy Test Results by Subject (Females Only)
(Page 13 of 15)

Subject Number	Subject Classification ^a	Timepoint	Result
098	F-NS	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
099	F-NS	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
100	F-NS	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
101	F-NS	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
102	F-NS	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative

^a Subject Classification: F-NS = Female, Non-Smoker; F-S = Female, Smoker.

Listing 16.5-20
Pregnancy Test Results by Subject (Females Only)
(Page 14 of 15)

Subject Number	Subject Classification ^a	Timepoint	Result
103	F-NS	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
500	F-NS	Week 6	Negative
		Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
501	F-NS	Week 3	Negative
		Week 6	Negative
		Screening	Negative
		Enrollment	Negative
		Week 1	Negative
502	F-S	Week 2	Negative
		Week 3	Negative
		Week 6	Negative
		Screening	Negative
		Enrollment	Negative
503	F-S	Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
		Screening	Negative

^a Subject Classification: F-NS= Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-20
Pregnancy Test Results by Subject (Females Only)
(Page 15 of 15)

Subject Number	Subject Classification ^a	Timepoint	Result
504	F-S	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
505	F-NS	Screening	NA
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative
506	F-S	Screening	Negative
		Enrollment	Negative
		Week 1	Negative
		Week 2	Negative
		Week 3	Negative
		Week 6	Negative

^a Subject Classification: F-NS= Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-22
Chemistry Laboratory Data by Subject: Metabolic Substrates
(Page 1 of 23)

Subject Number	Subject Classification ^a	Timepoint	Albumin (g/dL)	Cholesterol (mg/dL)	Glucose (mg/dL)	Total Protein (g/dL)	Triglycerides (mg/dL)
001	F-S	Screening	3.4	228 H	88	7.2	241 H
		Enrollment	3.6	209	87	7.2	324 H
		Week 1		226 H			293 H
		Week 3		245 H			402 H
		Week 6		195			267 H
002	F-S	Screening	3.6	244	75	7.3	390 H
		Enrollment	4.1	263	91	7.9	380 H
		Week 1		256			351 H
		Week 3		223			336 H
		Week 6		234			314 H
003	F-S	Screening	4.4	185	84	7.7	107
		Enrollment	4.1	158	81	6.9	108
		Week 1		162			116
		Week 3		156			87
		Week 6		169			111
004	F-S	Screening	4.5	254	88	7.4	109
		Enrollment	4.5	224	111	7.6	99
		Week 1		236			137
		Week 3		228			115
		Week 6		231			121
005	F-S	Screening	4.3	224	87	8.4	67
		Enrollment	3.8	189	83	7.3	57
		Week 1		196			70
		Week 3		199			79
		Week 6		212			58
006	F-S	Screening	4.4	193	95	7.7	122
		Enrollment	4.6	186	101	7.8	170
		Week 1		202			299 H
		Week 3		216			204
		Week 6		160 L			141

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-22
Chemistry Laboratory Data by Subject: Metabolic Substrates
(Page 2 of 23)

Subject Number	Subject Classification ^a	Timepoint	Albumin (g/dL)	Cholesterol (mg/dL)	Glucose (mg/dL)	Total Protein (g/dL)	Triglycerides (mg/dL)
007	F-S	Screening	4.3	233	95	7.1	179
		Enrollment	4.2	227	90	7.1	135
		Week 1		255			121
		Week 3		219			245 H
		Week 6		218			153
008	F-S	Screening	4.4	182	88	7.2	81
		Enrollment	4.3	172	99	6.9	75
		Week 1		175			95
		Week 3		157			71
		Week 6		182			62
009	F-S	Screening	4.3	207	95	7.6	82
		Enrollment	4.5	185 L	100	7.5	68
		Week 1		195			118
		Week 3		174 L			90
		Week 6		181 L			131
010	F-S	Screening	4.2	156	93	7.0	79
		Enrollment	4.3	135	83	6.8	66
		Week 1		147			74
011	F-S	Screening	4.0	165 L	97	6.8	51 L
		Enrollment	4.0	179	105	6.7	74
		Week 1		185			148
		Week 3		165 L			68
		Week 6		187			75
012	F-S	Screening	4.2	194	85	7.4	222 H
		Enrollment	4.5	187	100	7.9	136
		Week 1		219			459 H
		Week 3		194			137
		Week 6		189			109
013	F-S	Screening	5.0 H	210	88	7.7	107
		Enrollment	4.6	209	84	7.4	103
		Week 1		236 H			78
		Week 3		198			75
		Week 6		221 H			93

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-22
Chemistry Laboratory Data by Subject: Metabolic Substrates
(Page 3 of 23)

Subject Number	Subject Classification ^a	Timepoint	Albumin (g/dL)	Cholesterol (mg/dL)	Glucose (mg/dL)	Total Protein (g/dL)	Triglycerides (mg/dL)
014	F-S	Screening	4.2	191	90	7.3	102
		Screening (R)	4.1		96	7.3	
		Enrollment	4.1	187	82	7.1	92
		Week 1		211			87
		Week 3		194			88
		Week 6		173			58
015	F-S	Screening	4.1	156	88	7.8	150
		Enrollment	4.1	161	80	7.8	182 H
		Week 1		170			103
		Week 3		148			101
		Week 6		154			108
016	F-S	Screening	4.5	210	99	7.4	131
		Enrollment	4.5	197	85	7.2	69
		Week 1		192			70
		Week 3		195			119
		Week 6		197			86
017	F-S	Screening	4.3	195	89	7.7	90
		Enrollment	4.3	157	97	7.4	128
		Week 1		187			97
		Week 3		161			119
		Week 6		166			188
018	F-S	Screening	4.0	153	82	7.3	104
		Enrollment	4.0	122 L	83	7.1	78
		Week 1		130			93
		Week 3		139			102
		Week 6		143			160 H
019	F-S	Screening	4.0	145	86	6.9	72
		Enrollment	4.0	142	95	6.7	86
		Week 1		132			60
		Week 3		160			102
		Week 6		146			103

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-22
Chemistry Laboratory Data by Subject: Metabolic Substrates
(Page 4 of 23)

Subject Number	Subject Classification ^a	Timepoint	Albumin (g/dL)	Cholesterol (mg/dL)	Glucose (mg/dL)	Total Protein (g/dL)	Triglycerides (mg/dL)
020	F-S	Screening	4.1	201	96	7.0	90
		Enrollment	4.3	187	109	7.0	160
		Week 1		200			186
		Week 3		202			84
		Week 6		214			99
021	F-S	Screening	3.9	154	83	7.4	86
		Enrollment	4.2	148	90	7.1	162 H
		Week 1		139			186 H
		Week 3		146			225 H
		Week 6		125 L			162 H
022	F-S	Screening	4.1	170	88	7.2	165 H
		Enrollment	4.1	167	90	7.3	98
		Week 1		149			180 H
		Week 3		164			126
		Week 6		165			168 H
023	F-S	Screening	4.2	188	99	6.8	81
		Enrollment	4.2	157	91	6.8	47
		Week 1		184			60
		Week 3		185			167
		Week 6		167			96
024	F-S	Screening	4.2	212	99	7.6	124
		Enrollment	4.3	189	105	7.3	150
		Week 1		186			94
		Week 3		196			228 H
		Week 6		211			148
025	F-S	Screening	3.5	285	93	7.4	227
		Enrollment	3.7	312 H	114	7.8	252
		Week 1		323 H			274 H
		Week 3		294 H			303 H
		Week 6		307 H			240

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-22
Chemistry Laboratory Data by Subject: Metabolic Substrates
(Page 5 of 23)

Subject Number	Subject Classification ^a	Timepoint	Albumin (g/dL)	Cholesterol (mg/dL)	Glucose (mg/dL)	Total Protein (g/dL)	Triglycerides (mg/dL)
026	F-S	Screening	4.3	207	88	7.5	72
		Enrollment	3.9	215	95	7.1	98
		Week 1		214			118
		Week 3		188			110
		Week 6		179			85
027	F-S	Screening	4.1	174	83	6.8	50
		Enrollment	4.3	210	93	7.3	50
		Week 1		197			56
		Week 3		178			49
		Week 6		170			54
028	F-S	Screening	4.2	190	88	7.2	267 H
		Enrollment	3.9	178	83	6.6	244 H
		Week 1		236 H			248 H
		Week 3		189			292 H
		Week 6		157			179 H
029	F-S	Screening	4.1	174	90	7.3	121
		Enrollment	4.1	179	86	7.2	199 H
		Week 1		237 H			168 H
		Week 3		161			146 H
		Week 6		164			195 H
030	F-S	Screening	4.2	222	88	7.2	124
		Enrollment	4.0	202	84	6.5	154
		Week 1		197			383 H
		Week 3		189			158
		Week 6		221			345 H
031	F-S	Screening	3.8	182	92	7.0	95
		Enrollment	4.2	204	89	7.4	122
		Week 1		212			106
		Week 3		218			92
		Week 6		211			129

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.3-22
Chemistry Laboratory Data by Subject: Metabolic Substrates
(Page 6 of 23)

Subject Number	Subject Classification ^a	Timepoint	Albumin (g/dL)	Cholesterol (mg/dL)	Glucose (mg/dL)	Total Protein (g/dL)	Triglycerides (mg/dL)
032	F-S	Screening	3.9	163	89	6.4	122
		Enrollment	3.9	157	84	6.4	154 H
		Week 1		159			202 H
		Week 3		155			213 H
		Week 6		159			111
033	F-S	Screening	4.2	262 H	85	7.4	117
		Enrollment	4.2	201	84	7.3	144
		Week 1		209			161
		Week 3		235			94
		Week 6		242 H			111
034	F-S	Screening	4.1	235	79	7.1	102
		Enrollment	4.2	253 H	78	7.2	210 H
		Week 1		263 H			205 H
		Week 3		259 H			182 H
		Week 6		292 H			330 H
035	F-S	Screening	4.0	213	89	6.6	202
		Enrollment	4.0	197	85	6.6	176
		Week 1		213			214
		Week 3		220			215 H
		Week 6		234			290 H
036	M-S	Screening	4.6	230	94	7.5	168
		Enrollment	4.6	199	86	7.1	140
		Week 1		205			251
		Week 3		205			193
		Week 6		226			187
037	M-S	Screening	4.4	178	92	7.2	75
		Enrollment	4.0	150	96	6.7	74
		Week 1		171			76
		Week 3		164			70
		Week 6		194			59

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-22
Chemistry Laboratory Data by Subject: Metabolic Substrates
(Page 7 of 23)

Subject Number	Subject Classification ^a	Timepoint	Albumin (g/dL)	Cholesterol (mg/dL)	Glucose (mg/dL)	Total Protein (g/dL)	Triglycerides (mg/dL)
038	M-S	Screening	4.2	191	86	7.3	95
		Enrollment	3.9	177	94	7.1	63
		Week 1		212			90
		Week 3		208			170
		Week 6		221			53
039	M-S	Screening	4.6	278	110	7.7	372 H
		Enrollment	4.3	250	108	7.6	310
		Week 1		289			710 H
		Week 3		227			378 H
		Week 6		159 L			185
040	M-S	Screening	4.8	171	88	7.5	68
		Enrollment	5.0 H	184	90	8.0	71
		Week 1		180			88
		Week 3		181			57
		Week 6		191			114
041	M-S	Screening	4.2	199	96	7.5	66
		Enrollment	4.4	220	83	8.0	114
		Week 1		216			326
		Week 3		216			171
		Week 6		232			219
042	M-S	Screening	4.5	213	96	7.3	246
		Enrollment	4.8	210	92	7.5	213
		Week 1		201			159
		Week 3		193			108
		Week 6		200			256 H
043	M-S	Screening	4.8	196	91	7.9	54
		Enrollment	4.6	160	84	7.7	132
		Week 1		176			88
		Week 3		157			110
		Week 6		177			114

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-22
Chemistry Laboratory Data by Subject: Metabolic Substrates
(Page 8 of 23)

Subject Number	Subject Classification ^a	Timepoint	Albumin (g/dL)	Cholesterol (mg/dL)	Glucose (mg/dL)	Total Protein (g/dL)	Triglycerides (mg/dL)
044	M-S	Screening	5.2 H	256	93	7.8	207
		Enrollment	4.5	185	96	6.6	96
		Week 1		235			87
		Week 3		197			92
		Week 6		138 L			98
045	M-S	Screening	4.8	158	99	7.9	76
		Enrollment	4.8	146	101	7.4	106
		Week 1		184			103
		Week 3		137			133
		Week 6		156			151
046	M-S	Screening	4.4	183	79	7.2	169
		Enrollment	4.6	203	74	7.5	269 H
		Week 1		197			170
		Week 3		195			389 H
		Week 6		222			268 H
047	M-S	Screening	4.5	177	98	7.6	90
		Enrollment	4.6	163	95	7.4	81
		Week 1		173			149
		Week 3		170			88
		Week 6		166			92
048	M-S	Screening	4.5	231	94	8.0	137
		Enrollment	4.6	226	89	7.9	196
		Week 1		237 H			160
		Week 3		185			129
		Week 6		221			308 H
049	M-S	Screening	4.4	259	99	7.7	75
		Enrollment	4.1	254	96	7.4	102
		Week 1		236			80
		Week 3		256			107
		Week 6		213			74

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-22
Chemistry Laboratory Data by Subject: Metabolic Substrates
(Page 9 of 23)

Subject Number	Subject Classification ^a	Timepoint	Albumin (g/dL)	Cholesterol (mg/dL)	Glucose (mg/dL)	Total Protein (g/dL)	Triglycerides (mg/dL)
050	M-S	Screening	4.4	195	76	7.9	40 L
		Enrollment	4.1	171	74	7.4	53
		Week 1		192			92
		Week 3		198			137
		Week 6		184			106
051	M-S	Screening	4.5	126 L	92	7.4	80
		Screening (U)	4.4		97	7.0	
		Enrollment	4.6	125 L	88	7.0	52
052	M-S	Screening	4.7	212	91	7.4	135
		Enrollment	4.7	209	86	7.5	122
		Week 1		228			264
		Week 3		209			180
		Week 6		235			207
053	M-S	Screening	4.6	168	93	7.5	44 L
		Enrollment	4.4	206	97	7.6	94
054	M-S	Screening	4.5	118 L	98	7.5	88
		Enrollment	4.2	128	97	7.0	76
		Week 1		155			98
		Week 3		143			69
		Week 6		129			87
055	M-S	Screening	4.9	243	88	8.4	122
		Enrollment	4.3	224	90	7.3	102
		Week 1		252			172
		Week 3		231			109
		Week 6		225			141
056	M-S	Screening	4.3	249	98	7.3	104
		Enrollment	4.1	247	190 H	7.3	89
		Enrollment (U)	4.3		84	7.7	
		Week 1		238			185
		Week 3		227			127
		Week 6		271			157

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-22
Chemistry Laboratory Data by Subject: Metabolic Substrates
(Page 10 of 23)

Subject Number	Subject Classification ^a	Timepoint	Albumin (g/dL)	Cholesterol (mg/dL)	Glucose (mg/dL)	Total Protein (g/dL)	Triglycerides (mg/dL)
057	M-S	Screening	4.4	141	94	7.5	129
		Enrollment	4.1	147	89	7.0	123
		Week 1		124 L			165
		Week 3		132			140
		Week 6		137			106
058	M-S	Screening	4.6	232	93	7.6	80
		Enrollment	4.6	188	85	7.0	76
		Week 1		215			138
		Week 3		230			100
		Week 6		206			134
059	M-S	Screening	4.8	175	90	7.7	70
		Enrollment	4.3	178	100	7.4	65
		Week 1		189			58
		Week 3		182			60
		Week 6		171			85
060	M-S	Screening	4.4	241 H	100	7.3	207
		Enrollment	4.4	258 H	100	7.6	172
		Week 1		260 H			181
		Week 3		229			183
		Week 6		249 H			284 H
061	M-S	Screening	5.0 H	208	93	7.5	215
		Enrollment	5.0 H	188	93	7.4	203
		Week 1		221			251 H
		Week 3		183			202
		Week 6		201			109
062	M-S	Screening	4.9	291 H	107	8.3	322
		Enrollment	4.6	252	104	7.8	272
		Week 1		225			248
		Week 3		254			397 H
		Week 6		239			384 H

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-22
Chemistry Laboratory Data by Subject: Metabolic Substrates
(Page 11 of 23)

Subject Number	Subject Classification*	Timepoint	Albumin (g/dL)	Cholesterol (mg/dL)	Glucose (mg/dL)	Total Protein (g/dL)	Triglycerides (mg/dL)
063	M-S	Screening	4.6	196	100	7.5	105
		Enrollment	4.2	190	100	6.8	172
		Week 1		205			140
		Week 3		197			192
		Week 6		167			87
065	M-S	Screening	4.6	182	90	7.0	90
		Enrollment	4.4	164	83	7.1	153
		Week 1		164			109
		Week 3		200			83
		Week 6		210			148
066	M-S	Screening	4.5	266	98	7.7	194
		Enrollment	4.3	249	78	7.2	147
067	M-S	Screening	5.0 H	206	96	7.7	117
		Enrollment	4.7	196	85	7.6	89
		Week 1		152			139
		Week 3		233			118
		Week 6		193			127
068	M-S	Screening	4.7	138 L	91	7.5	103
		Enrollment	4.6	136 L	91	7.7	55
		Week 1		155			82
		Week 3		159			48 L
		Week 6		134 L			99
069	M-S	Screening	4.7	130	87	7.3	147
		Enrollment	4.6	162	95	7.4	210
		Week 1		120 L			121
		Week 3		167			149
		Week 6		141			91
071	F-NS	Screening	4.4	168	95	7.2	60
		Enrollment	4.4	182	89	7.3	103
		Week 1		179			103
		Week 3		185			66
		Week 6		165			78

* Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-22
Chemistry Laboratory Data by Subject: Metabolic Substrates
(Page 12 of 23)

Subject Number	Subject Classification ^a	Timepoint	Albumin (g/dL)	Cholesterol (mg/dL)	Glucose (mg/dL)	Total Protein (g/dL)	Triglycerides (mg/dL)
072	F-NS	Screening	4.2	198	93	7.7	102
		Enrollment	3.7	138 L	111	6.7	67
		Week 1		174			148
		Week 3		168			89
		Week 6		173			110
073	F-NS	Screening	4.0	187	85	6.9	100
		Enrollment	4.1	195	84	6.8	122
		Week 1		209			97
		Week 3		194			187 H
		Week 6		182			104
074	F-NS	Screening	4.2	192	86	7.3	122
		Enrollment	4.1	142	91	7.0	99
		Week 1		180			107
		Week 3		193			147 H
		Week 6		168			94
075	F-NS	Screening	3.9	150	84	7.4	36 L
		Enrollment	3.9	143	91	7.3	29 L
		Week 1		170			43
		Week 3		171			45
		Week 6		159			43
076	F-NS	Screening	4.3	264 H	99	7.7	82
		Enrollment	4.1	219 H	95	7.7	86
		Week 1		297 H			112
		Week 3		220 H			83
		Week 6		248 H			116
077	F-NS	Screening	4.1	156	84	7.3	68
		Enrollment	4.5	150	89	7.4	52
		Week 1		156			64
		Week 3		138			67
		Week 6		139			64

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-22
Chemistry Laboratory Data by Subject: Metabolic Substrates
(Page 13 of 23)

Subject Number	Subject Classification ^a	Timepoint	Albumin (g/dL)	Cholesterol (mg/dL)	Glucose (mg/dL)	Total Protein (g/dL)	Triglycerides (mg/dL)
078	F-NS	Screening	4.2	141	86	7.2	41
		Enrollment	4.3	150	90	7.2	60
		Week 1		155			72
		Week 3		158			70
		Week 6		158			47
079	F-NS	Screening	4.0	205	82	6.9	84
		Enrollment	4.2	223	82	7.0	97
		Week 1		224			93
		Week 3		230			101
		Week 6		223			128
080	F-NS	Screening	3.7	257	96	6.8	116
		Enrollment	3.7	235	98	6.8	88
		Week 1		192			105
		Week 3		220			86
		Week 6		257			125
081	F-NS	Screening	4.6	162	87	7.2	81
		Enrollment	4.8	164	81	7.1	39 L
		Week 1		182			196
		Week 3		159			153
		Week 6		159			112
082	F-NS	Screening	4.1	186	78	7.3	42
		Enrollment	3.9	162	85	6.9	48
		Week 1		206			88
		Week 3		172			35 L
		Week 6		183			60
083	F-NS	Screening	4.3	196	86	7.3	56
		Enrollment	4.3	200	82	7.3	58
		Week 1		202			64
		Week 3		196			93
		Week 6		180			55

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-22
Chemistry Laboratory Data by Subject: Metabolic Substrates
(Page 14 of 23)

Subject Number	Subject Classification*	Timepoint	Albumin (g/dL)	Cholesterol (mg/dL)	Glucose (mg/dL)	Total Protein (g/dL)	Triglycerides (mg/dL)
084	F-NS	Screening	4.0	223	94	7.7	75
		Enrollment	4.1	224	101	7.4	82
		Week 1		210			157
		Week 3		224			71
		Week 6		235			69
085	F-NS	Screening	4.0	141	93	7.0	175 H
		Enrollment	4.5	185	98	7.8	215 H
		Week 1		167			216 H
		Week 3		168			338 H
		Week 6		145			200 H
086	F-NS	Screening	4.0	230 H	92	8.0	96
		Enrollment	3.9	208	96	7.4	123
		Week 1		210			110
		Week 3		214			67
		Week 6		193			91
087	F-NS	Screening	4.6	271	87	7.5	125
		Enrollment	4.7	274	106	7.7	117
		Week 1		290			107
		Week 3		253			109
		Week 6		270			188
088	F-NS	Screening	3.8	215	98	8.2	92
		Enrollment	4.4	186	92	7.4	106
		Week 1		181			119
		Week 3		182			141
		Week 6		221			96
089	F-NS	Screening	4.0	184	92	6.8	69
		Enrollment	3.9	172	93	6.5	79
		Week 1		185			99
		Week 3		185			56
		Week 6		207			90

* Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-22
Chemistry Laboratory Data by Subject: Metabolic Substrates
(Page 15 of 23)

Subject Number	Subject Classification ^a	Timepoint	Albumin (g/dL)	Cholesterol (mg/dL)	Glucose (mg/dL)	Total Protein (g/dL)	Triglycerides (mg/dL)
090	F-NS	Screening	4.2	218	105	7.3	130
		Enrollment	4.4	232	113	7.3	140
		Week 1		228			187
		Week 3		234			171
		Week 6		234			175
091	F-NS	Screening	4.5	232	95	7.3	179
		Enrollment	4.5	271	107	7.5	191
		Week 1		267			209
		Week 3		235			309 H
		Week 6		227			207
092	F-NS	Screening	4.1	172	81	7.4	118
		Enrollment	4.2	174	85	7.8	129
		Week 1		181			137
		Week 3		170			141
		Week 6		185			139
093	F-NS	Screening	4.4	158	89	7.4	112
		Enrollment	4.2	164	88	7.1	48
		Week 1		179			87
		Week 3		156			72
		Week 6		170			94
094	F-NS	Screening	4.8	140	82	8.1	71
		Enrollment	4.9	150	90	7.9	54
		Week 1		166			98
		Week 3		167			50
		Week 6		158			115
095	F-NS	Screening	4.6	278	101	7.8	149
		Enrollment	4.1	256	95	6.9	150
		Week 1		301			207
		Week 3		250			231
		Week 6		270			130

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-22
Chemistry Laboratory Data by Subject: Metabolic Substrates
(Page 16 of 23)

Subject Number	Subject Classification ^a	Timepoint	Albumin (g/dL)	Cholesterol (mg/dL)	Glucose (mg/dL)	Total Protein (g/dL)	Triglycerides (mg/dL)
096	F-NS	Screening	4.1	158	96	7.6	107
		Enrollment	3.9	162	83	7.3	90
		Week 1		141			97
		Week 3		151			97
		Week 6		173			73
097	F-NS	Screening	4.1	184	98	7.4	159
		Enrollment	4.2	199	94	7.1	124
		Week 1		178			129
		Week 3		214			142
		Week 6		169			159
098	F-NS	Screening	4.1	186	76	7.3	73
		Enrollment	4.5	192	88	7.0	69
		Week 1		196			68
		Week 3		188			129
		Week 6		167			57
099	F-NS	Screening	4.1	196	94	7.5	130
		Enrollment	3.9	198	87	7.2	156 H
		Week 1		200			97
		Week 3		208			112
		Week 6		212			100
100	F-NS	Screening	4.5	264 H	87	8.0	50
		Enrollment	4.4	207	83	7.5	92
		Week 1		225			122
		Week 3		232			195 II
		Week 6		176			230 H
101	F-NS	Screening	4.6	170	97	8.2	112
		Enrollment	4.5	168	89	8.0	104
		Week 1		142			90
		Week 3		153			114
		Week 6		152			71

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-22
Chemistry Laboratory Data by Subject: Metabolic Substrates
(Page 17 of 23)

Subject Number	Subject Classification ^a	Timepoint	Albumin (g/dL)	Cholesterol (mg/dL)	Glucose (mg/dL)	Total Protein (g/dL)	Triglycerides (mg/dL)
102	F-NS	Screening	4.4	233	92	8.2	102
		Enrollment	4.0	191	96	7.4	94
		Week 1		191			149
		Week 3		210			176
		Week 6		239			128
103	F-NS	Screening	4.0	253 H	90	7.9	136
		Enrollment	4.0	261 H	95	7.7	196 H
		Week 1		259 H			216 H
		Week 3		251 H			152 H
		Week 6		209			231 H
104	M-NS	Screening	4.2	144	86	8.0	83
		Enrollment	4.5	164	83	7.8	93
		Week 1		181			116
		Week 3		147			152
		Week 6		163			74
105	M-NS	Screening	4.7	175	86	7.8	91
		Enrollment	5.0 H	206	83	8.3	129
		Week 1		214			157
		Week 3		175			140
		Week 6		169			243
106	M-NS	Screening	4.4	199	94	7.5	106
		Enrollment	4.7	185	85	7.7	96
		Week 1		220			123
		Week 3		196			103
		Week 6		187			142
107	M-NS	Screening	4.5	207	89	7.4	77
		Enrollment	4.6	199	91	7.5	98
		Week 1		178			124
		Week 3		223			169
		Week 6		192			87

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-22
Chemistry Laboratory Data by Subject: Metabolic Substrates
(Page 18 of 23)

Subject Number	Subject Classification ^a	Timepoint	Albumin (g/dL)	Cholesterol (mg/dL)	Glucose (mg/dL)	Total Protein (g/dL)	Triglycerides (mg/dL)
108	M-NS	Screening	4.3	154	98	7.3	183
		Enrollment	3.9	161	93	6.8	174
		Week 1		179			231
		Week 3		172			282
		Week 6		210			161
109	M-NS	Screening	4.9	218	95	8.1	240
		Enrollment	4.4	165	112	7.3	72
		Week 1		218			161
		Week 3		171			156
		Week 6		207			186
110	M-NS	Screening	4.1	233	103	6.9	84
		Enrollment	4.1	228	87	6.7	89
		Week 1		242			165
		Week 3		267			191
		Week 6		289 II			185
111	M-NS	Screening	4.4	224	100	7.8	128
		Enrollment	4.7	188	94	7.8	121
		Week 1		192			90
		Week 3		151			104
		Week 6		205			157
112	M-NS	Screening	4.4	232	95	7.4	62
		Enrollment	4.1	219	90	7.3	97
		Week 1		230			124
		Week 3		211			78
		Week 6		219			269
113	M-NS	Screening	4.2	191	89	6.9	134
		Enrollment	4.3	179	93	7.2	86
		Week 1		150 I.			52 L
114	M-NS	Screening	4.4	173	95	7.8	66
		Enrollment	4.5	172	88	7.8	94
		Week 1		194			82
		Week 3		190			59
		Week 6		180			129

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-22
Chemistry Laboratory Data by Subject: Metabolic Substrates
(Page 19 of 23)

Subject Number	Subject Classification ^a	Timepoint	Albumin (g/dL)	Cholesterol (mg/dL)	Glucose (mg/dL)	Total Protein (g/dL)	Triglycerides (mg/dL)
115	M-NS	Screening	4.5	143 L	95	7.7	61
		Enrollment	4.4	155	89	7.4	53
		Week 1		161			56
		Week 3		141 L			44 L
		Week 6		131 L			57
116	M-NS	Screening	4.5	204	100	8.3	261 H
		Enrollment	4.4	199	93	7.9	99
		Week 1		178			211
		Week 3		193			113
		Week 6		187			158
117	M-NS	Screening	5.1 H	128 L	115	8.0	77
		Enrollment	5.6 H	120 L	93	8.0	61
		Week 1		114 L			85
		Week 3		126 L			69
		Week 6		112 L			109
118	M-NS	Screening	4.5	187	97	8.0	372 H
		Enrollment	4.3	180	89	7.6	151
		Week 1		217			363 H
		Week 3		170			216
		Week 6		169			223
119	M-NS	Screening	4.5	191	92	7.2	202
		Enrollment	4.3	193	96	7.1	123
		Week 1		194			494 H
		Week 3		212			247
		Week 6		209			244
120	M-NS	Screening	4.6	150	94	7.2	51
		Enrollment	4.8	161	89	7.1	57
		Week 1		162			48 L
		Week 3		157			70
		Week 6		187			150

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-22
Chemistry Laboratory Data by Subject: Metabolic Substrates
(Page 20 of 23)

Subject Number	Subject Classification ^a	Timepoint	Albumin (g/dL)	Cholesterol (mg/dL)	Glucose (mg/dL)	Total Protein (g/dL)	Triglycerides (mg/dL)
121	M-NS	Screening	4.7	154	104	7.5	71
		Enrollment	4.6	191	93	7.5	84
		Week 1		177			187
		Week 3		183			281
		Week 6		192			111
122	M-NS	Screening	5.0 H	143	81	8.3	162
		Enrollment	4.6	143	90	7.8	123
		Week 1		141			113
		Week 3		164			104
		Week 6		164			86
123	M-NS	Screening	4.5	223	92	7.5	116
		Enrollment	4.1	209	95	7.1	70
		Week 1		192			82
		Week 3		233			214
		Week 6		231			121
124	M-NS	Screening	4.6	154	93	7.3	86
		Enrollment	4.7	135	93	7.3	54
		Week 1		136			49
		Week 3		130			112
		Week 6		150			109
125	M-NS	Screening	4.6	225	76	7.4	198
		Enrollment	4.6	219	79	7.4	184
		Week 1		234			535 H
		Week 3		220			278 H
		Week 6		254 H			231
126	M-NS	Screening	4.1	173 L	105	7.0	98
		Enrollment	3.8	173 L	104	6.5	115
		Week 1		174 L			125
		Week 3		164 L			156
		Week 6		154 L			110

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-22
Chemistry Laboratory Data by Subject: Metabolic Substrates
(Page 21 of 23)

Subject Number	Subject Classification ^a	Timepoint	Albumin (g/dL)	Cholesterol (mg/dL)	Glucose (mg/dL)	Total Protein (g/dL)	Triglycerides (mg/dL)
127	M-NS	Screening	4.6	123 L	94	8.1	153
		Enrollment	4.3	119 L	91	7.4	126
		Week 1		133			184
		Week 3		120 L			262 H
		Week 6		109 L			93
128	M-NS	Screening	4.7	260	107	8.3	101
		Enrollment	4.5	234	106	7.7	87
		Week 1		254			194
		Week 3		240			103
		Week 6		246			106
129	M-NS	Screening	4.8	157	91	8.2	115
		Enrollment	4.4	173	93	7.7	260
		Week 1		173			170
		Week 3		152			166
		Week 6		164			210
130	M-NS	Screening	4.7	239	102	8.0	92
		Enrollment	4.2	222	91	7.2	63
		Week 1		231			89
		Week 3		260			87
		Week 6		248			86
131	M-NS	Screening	4.7	175	88	8.0	70
		Enrollment	4.5	183	86	7.3	56
		Week 1		178			79
		Week 3		161			93
		Week 6		177			148
132	M-NS	Screening	4.6	150	97	7.7	65
		Enrollment	4.6	162	101	7.7	91
		Week 1		167			135
		Week 3		152			144
		Week 6		140			93

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-22
Chemistry Laboratory Data by Subject: Metabolic Substrates
(Page 22 of 23)

Subject Number	Subject Classification ^a	Timepoint	Albumin (g/dL)	Cholesterol (mg/dL)	Glucose (mg/dL)	Total Protein (g/dL)	Triglycerides (mg/dL)
133	M-NS	Screening	5.0 H	139 L	92	8.1	55
		Enrollment	4.9	143 L	93	8.0	76
		Week 1		120 L			56
		Week 3		141 L			86
		Week 6		134 L			77
134	M-NS	Screening	5.0 H	106 L	90	7.9	67
		Enrollment	5.2 H	134	93	8.2	255 H
		Week 1		166			125
		Week 3		152			160
		Week 6		110 L			106
135	M-NS	Screening	5.2 H	142	110	8.4	100
		Enrollment	4.8	148	89	7.8	102
		Week 1		154			105
		Week 3		159			126
		Week 6		202			82
500	F-NS	Screening	4.2	205	90	7.5	108
		Enrollment	4.0	180	92	7.0	129
		Week 1		218			169 H
		Week 3		166			154 H
		Week 6		219 H			127
501	F-NS	Screening	4.2	175	93	7.0	83
		Enrollment	4.2	164	89	6.7	65
		Week 1		173			101
		Week 3		198			125
		Week 6		190			51
502	F-S	Screening	4.3	197	90	7.0	80
		Enrollment	4.4	197	89	7.3	78
		Week 1		204			122
		Week 3		211			109
		Week 6		229			115

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-22
Chemistry Laboratory Data by Subject: Metabolic Substrates
(Page 23 of 23)

Subject Number	Subject Classification ^a	Timepoint	Albumin (g/dL)	Cholesterol (mg/dL)	Glucose (mg/dL)	Total Protein (g/dL)	Triglycerides (mg/dL)
503	F-S	Screening	4.2	163	85	7.1	85
		Enrollment	4.1	137	81	7.0	101
		Week 1		147			111
		Week 3		125 L			91
		Week 6		153			124
504	F-S	Screening	4.2	219	89	7.0	99
		Enrollment	4.2	196	95	6.9	97
		Week 1		203			104
		Week 3		208			179
		Week 6		204			88
505	F-NS	Screening	3.9	186 L	95	6.6	49 L
		Enrollment	4.4	215	84	7.0	54 L
		Week 1		216			62
		Week 3		196			68
		Week 6		224			65
506	F-S	Screening	4.4	179	90	7.3	87
		Enrollment	4.6	166	87	7.6	83
		Week 1		165			121
		Week 3		177			316 H
		Week 6		174			165

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-23
Chemistry Laboratory Data by Subject: Hepatic Status Liver Function Tests
(Page 1 of 12)

Subject Number	Subject Classification ^a	Timepoint	Alkaline Phosphatase (U/L)	LDH (U/L)	AST (SGOT) (U/L)	ALT (SGPT) (U/L)	Total Bilirubin (mg/dL)
001	F-S	Screening	74	126	14	13	0.2
		Enrollment	69	168	16	12	0.3
002	F-S	Screening	126 B	76	18	18	0.3
		Enrollment	128 H	71	15	19	0.2
003	F-S	Screening	75	160	26	25	0.3
		Enrollment	62	149	18	21	0.3
004	F-S	Screening	59	123	20	15	0.5
		Enrollment	59	137	13	11	0.5
005	F-S	Screening	91	155	25	18	0.5
		Enrollment	79	124	14	13	0.3
006	F-S	Screening	59	120	22	17	0.4
		Enrollment	56	110	21	14	0.6
007	F-S	Screening	63	160	18	14	0.6
		Enrollment	61	175	16	17	0.5
008	F-S	Screening	60	161	17	18	0.4
		Enrollment	56	156	15	16	0.2
009	F-S	Screening	75	135	20	22	0.3
		Enrollment	72	176	23	22	0.3
010	F-S	Screening	66	122	19	12	0.6
		Enrollment	57	119	16	11	1.4 H
011	F-S	Screening	95	139	18	28	0.6
		Enrollment	112	150	14	19	0.8
012	F-S	Screening	53	170	17	23	0.2
		Enrollment	54	170	14	17	0.2

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-23
Chemistry Laboratory Data by Subject: Hepatic Status Liver Function Tests
(Page 2 of 12)

Subject Number	Subject Classification ^a	Timepoint	Alkaline Phosphatase (U/L)	LDH (U/L)	AST (SGOT) (U/L)	ALT (SGPT) (U/L)	Total Bilirubin (mg/dL)
013	F-S	Screening	48	176	19	10	0.5
		Enrollment	45	181	20	12	0.5
014	F-S	Screening	Hemolysis	Hemolysis	19	11	0.6
		Screening (R)	47	122	15	11	0.3
		Enrollment	48	135	16	11	0.4
015	F-S	Screening	95	147	18	12	0.4
		Enrollment	89	162	17	13	0.6
016	F-S	Screening	65	83	19	14	0.4
		Enrollment	62	88	17	15	0.4
017	F-S	Screening	64	134	35 H	20	1.8 H
		Screening (R)					1.7 H
018	F-S	Enrollment	54	125	32	15	1.5 H
		Screening	61	117	15	9	0.3
019	F-S	Enrollment	57	115	12	7	0.4
		Screening	87	186	20	17	0.5
020	F-S	Enrollment	92	185	18	17	0.5
		Screening	60	132	16	10	0.5
021	F-S	Enrollment	60	133	18	16	0.5
		Screening	54	134	16	7	0.5
022	F-S	Enrollment	50	136	16	11	0.5
		Screening	96	169	22	40 H	0.4
023	F-S	Enrollment	98	154	15	22	0.3
		Screening	70	133	14	12	0.2
023	F-S	Enrollment	67	144	12	12	0.3

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-23
Chemistry Laboratory Data by Subject: Hepatic Status Liver Function Tests
(Page 3 of 12)

Subject Number	Subject Classification ^a	Timepoint	Alkaline Phosphatase (U/L)	LDH (U/L)	AST (SGOT) (U/L)	ALT (SGPT) (U/L)	Total Bilirubin (mg/dL)
024	F-S	Screening	49	154	13	14	0.4
		Enrollment	48	148	15	17	0.3
025	F-S	Screening	69	198	12	11	<0.2 L
		Enrollment	78	204	13	13	0.3
026	F-S	Screening	65	215	22	23	0.5
		Enrollment	66	182	24	27	0.3
027	F-S	Screening	64	149	21	14	0.3
		Enrollment	58	160	23	18	0.4
028	F-S	Screening	39	100	16	9	0.5
		Enrollment	32	103	13	12	0.4
029	F-S	Screening	63	136	16	13	0.2
		Enrollment	59	146	16	13	0.4
030	F-S	Screening	47	122	17	17	0.3
		Enrollment	47	134	18	18	0.3
031	F-S	Screening	57	114	13	14	0.3
		Enrollment	60	107	14	12	0.4
032	F-S	Screening	93	180	16	12	0.2
		Enrollment	95	148	15	15	0.4
033	F-S	Screening	59	136	20	16	0.8
		Enrollment	58	153	22	18	0.5
034	F-S	Screening	68	150	12	11	0.3
		Enrollment	69	144	12	9	0.4
035	F-S	Screening	53	151	21	21	0.4
		Enrollment	52	159	19	18	0.4

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-23
Chemistry Laboratory Data by Subject: Hepatic Status Liver Function Tests
(Page 4 of 12)

Subject Number	Subject Classification ^a	Timepoint	Alkaline Phosphatase (U/L)	LDH (U/L)	AST (SGOT) (U/L)	ALT (SGPT) (U/L)	Total Bilirubin (mg/dL)
036	M-S	Screening	68	130	23	38	0.8
		Enrollment	67	131	21	27	1.0
037	M-S	Screening	83	143	20	14	0.5
		Enrollment	74	152	17	14	0.5
038	M-S	Screening	109	123	20	26	0.3
		Enrollment	108	120	17	34	0.4
039	M-S	Screening	87	135	21	23	0.5
		Enrollment	87	174	22	18	0.5
040	M-S	Screening	85	152	25	23	0.4
		Enrollment	83	163	19	18	0.5
041	M-S	Screening	65	126	17	17	0.3
		Enrollment	69	153	18	17	0.4
042	M-S	Screening	56	177	27	35	0.6
		Enrollment	55	166	25	36	0.7
043	M-S	Screening	75	115	18	21	0.5
		Enrollment	70	121	15	15	0.4
044	M-S	Screening	49	159	31	22	0.5
		Enrollment	46	161	28	23	0.3
045	M-S	Screening	48	127	22	16	0.4
		Enrollment	45	159	19	17	0.4
046	M-S	Screening	56	126	20	43	0.3
		Enrollment	58	140	23	49 H	0.4
047	M-S	Screening	66	228	14	10	0.5
		Enrollment	61	217	11	8	0.5

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-23
Chemistry Laboratory Data by Subject: Hepatic Status Liver Function Tests
(Page 5 of 12)

Subject Number	Subject Classification ^a	Timepoint	Alkaline Phosphatase (U/L)	LDH (U/L)	AST (SGOT) (U/L)	ALT (SGPT) (U/L)	Total Bilirubin (mg/dL)
048	M-S	Screening	67	85	26	42	0.3
		Enrollment	65	97	27	48 H	0.4
049	M-S	Screening	70	186	28	30	1.3 H
		Enrollment	76	204	31	29	0.5
050	M-S	Screening	50	171	24	19	0.6
		Enrollment	42	163	18	17	0.4
051	M-S	Screening	58	144	20	12	1.6 H
		Screening (U)	54	158	17	10	0.9
		Enrollment	65	171	23	18	2.0 H
052	M-S	Screening	63	126	21	26	0.6
		Enrollment	55	139	25	21	0.7
053	M-S	Screening	58	156	21	16	0.4
		Enrollment	59	168	20	17	0.5
054	M-S	Screening	67	157	19	20	1.0
		Enrollment	59	141	23	24	0.7
055	M-S	Screening	81	188	22	33	0.5
		Enrollment	76	163	17	25	0.5
056	M-S	Screening	102	128	19	12	0.4
		Enrollment	104	139	15	9	0.4
		Enrollment (U)	106	157	23	13	0.2
057	M-S	Screening	26 L	171	28	39	0.6
		Enrollment	23 L	142	22	33	0.4
058	M-S	Screening	60	158	21	21	0.9
		Enrollment	57	132	16	14	1.0

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-23
Chemistry Laboratory Data by Subject: Hepatic Status Liver Function Tests
(Page 6 of 12)

Subject Number	Subject Classification ^a	Timepoint	Alkaline Phosphatase (U/L)	LDH (U/L)	AST (SGOT) (U/L)	ALT (SGPT) (U/L)	Total Bilirubin (mg/dL)
059	M-S	Screening	63	178	24	16	1.1
		Enrollment	56	163	18	15	0.9
060	M-S	Screening	65	142	31	39	0.2
		Enrollment	66	173	42 H	43	0.3
061	M-S	Screening	72	116	20	27	0.5
		Enrollment	66	114	22	22	0.6
062	M-S	Screening	105	159	28	53 H	0.5
		Enrollment	104	182	33	55 H	0.5
063	M-S	Screening	56	154	25	26	0.3
		Enrollment	51	141	20	19	0.4
065	M-S	Screening	67	139	19	14	0.7
		Enrollment	71	140	20	18	0.3
066	M-S	Screening	69	144	17	16	0.3
		Enrollment	68	154	20	13	0.3
067	M-S	Screening	70	161	21	22	1.3 H
		Enrollment	70	164	22	29	1.1
068	M-S	Screening	61	141	18	18	0.5
		Enrollment	76	148	17	14	0.4
069	M-S	Screening	79	158	16	15	0.7
		Enrollment	88	116	13	9	0.5
071	F-NS	Screening	132 H	174	23	25	0.5
		Enrollment	124 H	185	19	23	0.3
072	F-NS	Screening	68	171	22	18	0.6
		Enrollment	58	178	19	13	0.3

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-23
Chemistry Laboratory Data by Subject: Hepatic Status Liver Function Tests
(Page 7 of 12)

Subject Number	Subject Classification ^a	Timepoint	Alkaline Phosphatase (U/L)	LDH (U/L)	AST (SGOT) (U/L)	ALT (SGPT) (U/L)	Total Bilirubin (mg/dL)
073	F-NS	Screening	67	148	17	12	0.5
		Enrollment	66	152	18	12	0.7
074	F-NS	Screening	59	144	26	25	0.7
		Enrollment	49	146	21	16	0.4
075	F-NS	Screening	63	188	23	16	0.4
		Enrollment	72	166	17	13	<0.2 L
076	F-NS	Screening	54	128	14	15	0.9
		Enrollment	47	142	14	18	0.5
077	F-NS	Screening	58	125	14	15	0.3
		Enrollment	51	110	12	11	0.3
078	F-NS	Screening	88	145	18	14	0.3
		Enrollment	87	125	16	14	0.4
079	F-NS	Screening	61	101	13	10	0.6
		Enrollment	63	106	14	8	0.5
080	F-NS	Screening	71	176	16	16	0.2
		Enrollment	67	182	14	11	0.3
081	F-NS	Screening	34	156	23	13	0.4
		Enrollment	32	151	21	14	0.5
082	F-NS	Screening	59	146	23	13	0.5
		Enrollment	45	180	14	12	0.5
083	F-NS	Screening	58	184	26	24	1.1
		Enrollment	57	159	20	17	1.3 H
084	F-NS	Screening	72	177	24	16	0.6
		Enrollment	64	197	22	16	0.5

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-23
Chemistry Laboratory Data by Subject: Hepatic Status Liver Function Tests
(Page 8 of 12)

Subject Number	Subject Classification*	Timepoint	Alkaline Phosphatase (U/L)	LDH (U/L)	AST (SGOT) (U/L)	ALT (SGPT) (U/L)	Total Bilirubin (mg/dL)
085	F-NS	Screening	41	133	16	15	0.4
		Enrollment	48	146	16	16	0.4
086	F-NS	Screening	39	132	18	16	0.3
		Enrollment	45	150	21	21	0.3
087	F-NS	Screening	60	160	30	36 H	0.4
		Enrollment	66	183	34	39 H	0.3
088	F-NS	Screening	53	150	23	26	0.4
		Enrollment	50	129	23	25	0.4
089	F-NS	Screening	58	152	21	11	0.3
		Enrollment	51	131	16	8	0.3
090	F-NS	Screening	69	214	20	19	0.5
		Enrollment	69	209	17	20	0.7
091	F-NS	Screening	58	185	21	15	0.4
		Enrollment	61	179	18	15	0.4
092	F-NS	Screening	47	143	19	17	0.3
		Enrollment	52	136	18	19	0.3
093	F-NS	Screening	61	164	34	38 H	0.2
		Enrollment	60	154	21	17	0.3
094	F-NS	Screening	57	162	20	19	0.5
		Enrollment	61	160	18	17	0.8
095	F-NS	Screening	52	134	21	20	0.3
		Enrollment	52	136	20	20	0.4
096	F-NS	Screening	60	144	22	13	0.7
		Enrollment	63	158	22	15	1.0

* Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-23
Chemistry Laboratory Data by Subject: Hepatic Status Liver Function Tests
(Page 9 of 12)

Subject Number	Subject Classification ^a	Timepoint	Alkaline Phosphatase (U/L)	LDH (U/L)	AST (SGOT) (U/L)	ALT (SGPT) (U/L)	Total Bilirubin (mg/dL)
097	F-NS	Screening	54	194	19	23	0.3
		Enrollment	58	166	14	19	0.5
098	F-NS	Screening	42	200	29	25	0.8
		Enrollment	45	200	22	21	0.5
099	F-NS	Screening	41	131	20	25	0.3
		Enrollment	44	122	16	19	0.4
100	F-NS	Screening	35	152	26	14	0.6
		Enrollment	37	137	20	11	0.4
101	F-NS	Screening	61	134	23	22	0.5
		Enrollment	55	136	20	18	0.3
102	F-NS	Screening	77	202	24	24	0.6
		Enrollment	65	197	34	50 H	0.5
103	F-NS	Screening	46	132	17	17	0.3
		Enrollment	50	135	17	15	0.3
104	M-NS	Screening	29 L	123	25	22	0.5
		Enrollment	26 L	135	26	28	0.8
105	M-NS	Screening	35	151	26	25	0.7
		Enrollment	38	140	19	18	0.5
106	M-NS	Screening	72	154	23	16	0.4
		Enrollment	73	182	24	17	0.4
107	M-NS	Screening	89	181	39 H	34	0.5
		Enrollment	91	171	30	19	0.5
108	M-NS	Screening	58	167	25	23	0.3
		Enrollment	61	138	22	19	0.5

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-23
Chemistry Laboratory Data by Subject: Hepatic Status Liver Function Tests
(Page 10 of 12)

Subject Number	Subject Classification ^a	Timepoint	Alkaline Phosphatase (U/L)	LDH (U/L)	AST (SGOT) (U/L)	ALT (SGPT) (U/L)	Total Bilirubin (mg/dL)
109	M-NS	Screening	55	166	24	41	0.8
		Enrollment	57	194	23	40	0.4
110	M-NS	Screening	71	143	29	38	0.4
		Enrollment	70	148	25	30	0.6
111	M-NS	Screening	52	138	23	29	0.7
		Enrollment	52	129	20	26	0.7
112	M-NS	Screening	51	133	18	16	0.4
		Enrollment	53	135	18	14	0.6
113	M-NS	Screening	61	127	19	17	0.4
		Enrollment	69	133	19	20	0.3
114	M-NS	Screening	77	157	22	15	1.0
		Enrollment	70	169	22	16	0.9
115	M-NS	Screening	95	267 H	37 H	38	0.5
		Enrollment	84	246 H	33	31	0.5
116	M-NS	Screening	74	156	28	40	0.5
		Enrollment	68	125	25	32	0.8
117	M-NS	Screening	52	179	24	27	0.5
		Enrollment	46	177	24	25	0.6
118	M-NS	Screening	53	135	24	23	<0.2 L
		Enrollment	52	138	20	16	0.2
119	M-NS	Screening	42	140	21	58 H	0.6
		Enrollment	45	147	19	38	0.6
120	M-NS	Screening	64	203	46 H	40	0.5
		Enrollment	69	198	23	21	0.8

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-23
Chemistry Laboratory Data by Subject: Hepatic Status Liver Function Tests
(Page 11 of 12)

Subject Number	Subject Classification ^a	Timepoint	Alkaline Phosphatase (U/L)	LDH (U/L)	AST (SGOT) (U/L)	ALT (SGPT) (U/L)	Total Bilirubin (mg/dL)
121	M-NS	Screening	76	168	28	13	0.5
		Enrollment	79	166	25	19	0.2
122	M-NS	Screening	65	132	17	13	0.5
		Enrollment	59	121	14	11	0.4
123	M-NS	Screening	54	195	29	21	0.6
		Enrollment	56	191	30	18	0.9
124	M-NS	Screening	67	129	18	11	0.9
		Enrollment	60	147	18	13	0.7
125	M-NS	Screening	86	229	26	41	0.6
		Enrollment	91	216	21	36	0.7
126	M-NS	Screening	55	124	16	15	0.5
		Enrollment	55	141	19	18	1.0
127	M-NS	Screening	86	124	29	26	0.5
		Enrollment	82	140	32	28	0.5
128	M-NS	Screening	68	122	19	17	0.8
		Enrollment	64	134	21	14	0.7
129	M-NS	Screening	96	151	21	18	0.6
		Enrollment	93	139	20	13	0.4
130	M-NS	Screening	61	146	23	26	1.1
		Enrollment	54	133	20	18	0.9
131	M-NS	Screening	53	145	27	30	0.9
		Enrollment	53	130	23	23	0.9
132	M-NS	Screening	74	178	23	23	0.7
		Enrollment	74	181	25	19	0.7

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-23
Chemistry Laboratory Data by Subject: Hepatic Status Liver Function Tests
(Page 12 of 12)

Subject Number	Subject Classification ^a	Timepoint	Alkaline Phosphatase (U/L)	LDH (U/L)	AST (SGOT) (U/L)	ALT (SGPT) (U/L)	Total Bilirubin (mg/dL)
133	M-NS	Screening	76	132	24	13	0.7
		Enrollment	82	141	22	12	0.5
134	M-NS	Screening	56	93	18	12	0.6
		Enrollment	70	115	22	14	0.5
135	M-NS	Screening	59	160	23	20	0.5
		Enrollment	60	151	17	12	0.7
500	F-NS	Screening	70	129	19	17	0.4
		Enrollment	67	126	17	16	0.2
501	F-NS	Screening	44	153	27	13	0.7
		Enrollment	50	161	21	13	0.5
502	F-S	Screening	49	119	15	11	0.5
		Enrollment	55	123	17	11	0.7
503	F-S	Screening	45	148	21	12	0.2
		Enrollment	52	134	20	11	0.3
504	F-S	Screening	79	140	15	18	0.3
		Enrollment	80	135	14	10	0.3
505	F-NS	Screening	68	155	20	18	0.7
		Enrollment	75	170	22	16	0.7
506	F-S	Screening	53	164	18	17	0.5
		Enrollment	50	158	18	15	0.5

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-24
Chemistry Laboratory Data by Subject: Renal Status Serum Metabolites
(Page 1 of 12)

Subject Number	Subject Classification ^a	Timepoint	BUN (mg/dL)	Creatinine (mg/dL)	Uric Acid (mg/dL)
001	F-S	Screening	9	0.7	6.8
		Enrollment	9	0.7	7.3 H
002	F-S	Screening	12	0.5	4.8
		Enrollment	11	0.6	4.1
003	F-S	Screening	10	0.7	4.5
		Enrollment	10	0.8	4.4
004	F-S	Screening	19	0.8	3.5
		Enrollment	14	0.8	2.9
005	F-S	Screening	12	0.9	5.4
		Enrollment	10	0.8	4.5
006	F-S	Screening	14	0.6	3.6
		Enrollment	13	0.7	4.0
007	F-S	Screening	12	0.7	3.9
		Enrollment	13	0.6	3.6
008	F-S	Screening	12	0.7	5.1
		Enrollment	8	0.7	3.8
009	F-S	Screening	15	0.7	4.4
		Enrollment	22	0.8	5.1
010	F-S	Screening	11	0.6	4.5
		Enrollment	11	0.6	4.7
011	F-S	Screening	14	0.7	3.7
		Enrollment	6	0.7	4.8
012	F-S	Screening	10	0.6	3.2
		Enrollment	14	0.7	3.5

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-24
Chemistry Laboratory Data by Subject: Renal Status Serum Metabolites
(Page 2 of 12)

Subject Number	Subject Classification ^a	Timepoint	BUN (mg/dL)	Creatinine (mg/dL)	Uric Acid (mg/dL)
013	F-S	Screening	11	0.8	3.3
		Enrollment	12	0.7	3.6
014	F-S	Screening	12	0.8	3.6
		Screening (R)	11	0.9	3.9
		Enrollment	11	0.8	4.1
015	F-S	Screening	11	0.7	3.9
		Enrollment	12	0.7	4.5
016	F-S	Screening	11	0.7	4.5
		Enrollment	8	0.6	4.0
017	F-S	Screening	15	0.8	4.6
		Enrollment	11	0.9	3.8
018	F-S	Screening	8	0.7	4.6
		Enrollment	9	0.7	4.2
019	F-S	Screening	11	0.8	4.6
		Enrollment	10	0.7	4.5
020	F-S	Screening	5	0.7	4.0
		Enrollment	8	0.6	4.5
021	F-S	Screening	8	0.6	4.7
		Enrollment	9	0.7	5.6
022	F-S	Screening	14	0.7	4.8
		Enrollment	13	0.7	4.4
023	F-S	Screening	23	0.7	2.6
		Enrollment	17	0.5	2.3
024	F-S	Screening	12	0.7	4.7
		Enrollment	10	0.7	4.8

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-24
Chemistry Laboratory Data by Subject: Renal Status Serum Metabolites
(Page 3 of 12)

Subject Number	Subject Classification ^a	Timepoint	BUN (mg/dL)	Creatinine (mg/dL)	Uric Acid (mg/dL)
025	F-S	Screening	15	0.9	5.2
		Enrollment	16	0.9	6.2
026	F-S	Screening	17	0.9	4.9
		Enrollment	19	0.8	4.4
027	F-S	Screening	9	0.6	3.9
		Enrollment	12	0.5	3.8
028	F-S	Screening	13	0.8	4.8
		Enrollment	9	0.7	3.6
029	F-S	Screening	9	0.7	4.7
		Enrollment	8	0.6	4.8
030	F-S	Screening	12	0.7	5.4
		Enrollment	10	0.5	5.1
031	F-S	Screening	6	0.6	3.7
		Enrollment	10	0.6	4.5
032	F-S	Screening	11	0.7	4.6
		Enrollment	11	0.7	4.9
033	F-S	Screening	10	0.7	5.4
		Enrollment	9	0.7	6.2
034	F-S	Screening	15	0.6	3.1
		Enrollment	15	0.7	4.1
035	F-S	Screening	11	0.7	5.0
		Enrollment	10	0.6	4.6
036	M-S	Screening	15	1.0	6.3
		Enrollment	15	1.0	5.8

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-24
Chemistry Laboratory Data by Subject: Renal Status Serum Metabolites
(Page 4 of 12)

Subject Number	Subject Classification ^a	Timepoint	BUN (mg/dL)	Creatinine (mg/dL)	Uric Acid (mg/dL)
037	M-S	Screening	11	0.9	4.6
		Enrollment	11	0.8	4.8
038	M-S	Screening	15	1.0	5.4
		Enrollment	18	1.0	4.7
039	M-S	Screening	18	0.8	7.2
		Enrollment	18	0.9	7.5
040	M-S	Screening	13	0.9	7.2
		Enrollment	17	1.0	7.3
041	M-S	Screening	15	0.9	4.2
		Enrollment	12	0.9	4.8
042	M-S	Screening	11	1.1	6.0
		Enrollment	13	1.1	7.1
043	M-S	Screening	8	1.1	7.4
		Enrollment	8	1.1	7.6
044	M-S	Screening	26 H	1.2	4.8
		Enrollment	19	1.1	4.1
045	M-S	Screening	12	0.8	6.0
		Enrollment	15	0.8	6.5
046	M-S	Screening	19	0.9	6.1
		Enrollment	13	1.0	8.0
047	M-S	Screening	8	1.1	6.7
		Enrollment	12	1.2	7.5
048	M-S	Screening	22	0.9	5.0
		Enrollment	24	1.0	5.2

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-24
Chemistry Laboratory Data by Subject: Renal Status Serum Metabolites
(Page 5 of 12)

Subject Number	Subject Classification ^a	Timepoint	BUN (mg/dL)	Creatinine (mg/dL)	Uric Acid (mg/dL)
049	M-S	Screening	11	0.8	4.4
		Enrollment	18	0.8	4.6
050	M-S	Screening	14	1.0	4.5
		Enrollment	12	0.9	4.0
051	M-S	Screening	17	0.8	4.6
		Screening (U)	16	0.8	4.1
		Enrollment	14	0.8	5.3
052	M-S	Screening	15	1.0	6.7
		Enrollment	18	1.0	7.8
053	M-S	Screening	10	0.6	3.4
		Enrollment	15	0.5	4.0
054	M-S	Screening	10	1.0	5.1
		Enrollment	11	0.9	4.5
055	M-S	Screening	15	0.8	5.6
		Enrollment	19	0.9	5.6
056	M-S	Screening	13	0.8	3.6
		Enrollment	19	0.9	3.8
		Enrollment (U)	14	0.9	4.3
057	M-S	Screening	15	0.9	7.3
		Enrollment	19	0.9	8.1
058	M-S	Screening	10	0.8	6.2
		Enrollment	9	0.8	6.0
059	M-S	Screening	14	0.8	6.0
		Enrollment	14	0.9	5.4
060	M-S	Screening	11	0.9	7.0
		Enrollment	16	1.0	8.0

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-24
Chemistry Laboratory Data by Subject: Renal Status Serum Metabolites
(Page 6 of 12)

Subject Number	Subject Classification ^a	Timepoint	BUN (mg/dL)	Creatinine (mg/dL)	Uric Acid (mg/dL)
061	M-S	Screening	13	1.0	6.4
		Enrollment	18	1.0	6.0
062	M-S	Screening	12	0.8	7.6
		Enrollment	10	0.9	8.2
063	M-S	Screening	17	1.1	6.5
		Enrollment	13	1.0	6.3
065	M-S	Screening	11	0.9	7.3
		Enrollment	12	0.9	7.3
066	M-S	Screening	10	0.9	4.3
		Enrollment	13	0.9	4.7
067	M-S	Screening	15	1.0	4.5
		Enrollment	14	1.0	4.5
068	M-S	Screening	10	0.7	4.2
		Enrollment	7	0.8	4.1
069	M-S	Screening	9	1.1	6.4
		Enrollment	19	1.0	6.2
071	F-NS	Screening	9	0.6	4.1
		Enrollment	10	0.7	4.0
072	F-NS	Screening	9	0.8	3.9
		Enrollment	9	0.8	4.4
073	F-NS	Screening	10	0.8	4.4
		Enrollment	11	0.7	3.8
074	F-NS	Screening	17	1.1	4.9
		Enrollment	11	1.0	4.1

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-24
Chemistry Laboratory Data by Subject: Renal Status Serum Metabolites
(Page 7 of 12)

Subject Number	Subject Classification ^a	Timepoint	BUN (mg/dL)	Creatinine (mg/dL)	Uric Acid (mg/dL)
075	F-NS	Screening	10	0.8	3.8
		Enrollment	8	0.8	3.3
076	F-NS	Screening	12	0.8	4.9
		Enrollment	8	0.7	4.5
077	F-NS	Screening	18	0.8	3.9
		Enrollment	16	0.9	4.4
078	F-NS	Screening	13	0.8	4.3
		Enrollment	10	0.8	3.6
079	F-NS	Screening	19	0.6	3.1
		Enrollment	12	0.6	2.2
080	F-NS	Screening	10	0.6	4.7
		Enrollment	10	0.8	4.9
081	F-NS	Screening	18	0.8	3.4
		Enrollment	19	0.7	3.5
082	F-NS	Screening	20	0.7	4.1
		Enrollment	15	0.7	3.6
083	F-NS	Screening	17	0.7	2.9
		Enrollment	12	0.6	2.8
084	F-NS	Screening	11	1.0	4.5
		Enrollment	14	0.8	5.3
085	F-NS	Screening	11	0.7	4.6
		Enrollment	15	0.7	4.8
086	F-NS	Screening	16	0.7	4.0
		Enrollment	16	0.7	4.5

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-24
Chemistry Laboratory Data by Subject: Renal Status Serum Metabolites
(Page 8 of 12)

Subject Number	Subject Classification ^a	Timepoint	BUN (mg/dL)	Creatinine (mg/dL)	Uric Acid (mg/dL)
087	F-NS	Screening	15	0.7	3.7
		Enrollment	16	0.7	4.1
088	F-NS	Screening	18	0.6	2.9
		Enrollment	12	0.7	3.2
089	F-NS	Screening	12	0.7	3.6
		Enrollment	10	0.7	3.9
090	F-NS	Screening	11	0.8	4.3
		Enrollment	16	0.9	4.9
091	F-NS	Screening	21	0.8	5.6
		Enrollment	17	0.8	5.5
092	F-NS	Screening	15	0.8	3.7
		Enrollment	12	0.8	3.5
093	F-NS	Screening	11	0.7	3.7
		Enrollment	7	0.6	3.8
094	F-NS	Screening	13	0.7	4.1
		Enrollment	11	0.7	4.2
095	F-NS	Screening	13	0.8	5.0
		Enrollment	15	0.8	5.8
096	F-NS	Screening	12	0.8	4.4
		Enrollment	15	0.6	3.6
097	F-NS	Screening	14	0.7	5.4
		Enrollment	14	0.7	4.8
098	F-NS	Screening	12	0.8	2.5
		Enrollment	14	0.7	2.1

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-24
Chemistry Laboratory Data by Subject: Renal Status Serum Metabolites
(Page 9 of 12)

Subject Number	Subject Classification ^a	Timepoint	BUN (mg/dL)	Creatinine (mg/dL)	Uric Acid (mg/dL)
099	F-NS	Screening	14	0.8	6.5
		Enrollment	17	0.8	5.3
100	F-NS	Screening	10	0.6	3.0
		Enrollment	11	0.8	2.1
101	F-NS	Screening	11	0.8	6.0
		Enrollment	8	0.7	5.9
102	F-NS	Screening	13	0.8	3.6
		Enrollment	11	0.8	3.8
103	F-NS	Screening	17	1.0	4.5
		Enrollment	21	0.9	3.9
104	M-NS	Screening	21	1.0	8.6 H
		Enrollment	20	1.1	7.9
105	M-NS	Screening	12	0.9	3.4
		Enrollment	14	0.9	3.4
106	M-NS	Screening	12	0.9	6.2
		Enrollment	11	1.1	7.0
107	M-NS	Screening	21	1.1	7.5
		Enrollment	20	1.2	6.8
108	M-NS	Screening	13	1.2	5.6
		Enrollment	12	1.1	5.6
109	M-NS	Screening	20	1.0	8.0
		Enrollment	18	0.9	8.3 H
110	M-NS	Screening	17	1.0	6.2
		Enrollment	14	1.0	6.3

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-24
Chemistry Laboratory Data by Subject: Renal Status Serum Metabolites
(Page 10 of 12)

Subject Number	Subject Classification ^a	Timepoint	BUN (mg/dL)	Creatinine (mg/dL)	Uric Acid (mg/dL)
111	M-NS	Screening	16	1.1	7.6
		Enrollment	17	1.0	7.7
112	M-NS	Screening	16	0.9	4.8
		Enrollment	18	1.1	5.9
113	M-NS	Screening	13	0.8	3.7
		Enrollment	20	0.9	4.5
114	M-NS	Screening	9	1.3 H	5.3
		Enrollment	8	1.2	6.6
115	M-NS	Screening	12	0.8	4.3
		Enrollment	18	0.8	4.7
116	M-NS	Screening	19	1.1	8.6 H
		Enrollment	18	0.9	5.9
117	M-NS	Screening	22	0.9	5.0
		Enrollment	20	1.0	6.2
118	M-NS	Screening	14	0.8	5.3
		Enrollment	11	0.8	6.1
119	M-NS	Screening	16	1.1	8.2
		Enrollment	14	0.9	6.6
120	M-NS	Screening	22	1.0	6.0
		Enrollment	27 H	0.9	6.8
121	M-NS	Screening	11	1.1	4.7
		Enrollment	14	1.1	4.9
122	M-NS	Screening	11	0.8	5.6
		Enrollment	15	0.8	6.1

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-24
Chemistry Laboratory Data by Subject: Renal Status Serum Metabolites
(Page 11 of 12)

Subject Number	Subject Classification ^a	Timepoint	BUN (mg/dL)	Creatinine (mg/dL)	Uric Acid (mg/dL)
123	M-NS	Screening	19	1.1	3.8
		Enrollment	19	1.1	4.3
124	M-NS	Screening	15	1.2	6.1
		Enrollment	15	1.1	6.6
125	M-NS	Screening	26 ^H	1.0	6.9
		Enrollment	23	0.8	6.6
126	M-NS	Screening	14	0.8	4.4
		Enrollment	16	0.8	4.9
127	M-NS	Screening	11	1.1	5.7
		Enrollment	14	1.0	5.6
128	M-NS	Screening	16	1.1	7.1
		Enrollment	15	0.9	6.5
129	M-NS	Screening	14	0.9	4.7
		Enrollment	17	0.9	3.8
130	M-NS	Screening	15	1.0	5.0
		Enrollment	16	1.0	5.2
131	M-NS	Screening	13	1.0	5.2
		Enrollment	14	0.9	5.3
132	M-NS	Screening	17	0.9	5.9
		Enrollment	14	0.8	5.7
133	M-NS	Screening	9	0.9	6.2
		Enrollment	11	0.9	5.9
134	M-NS	Screening	9	0.7	4.3
		Enrollment	9	0.8	5.6

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-24
Chemistry Laboratory Data by Subject: Renal Status Serum Metabolites
(Page 12 of 12)

Subject Number	Subject Classification ^a	Timepoint	BUN (mg/dL)	Creatinine (mg/dL)	Uric Acid (mg/dL)
135	M-NS	Screening	13	0.9	3.9
		Enrollment	12	0.8	3.2
500	F-NS	Screening	13	0.9	5.9
		Enrollment	10	0.9	6.2
501	F-NS	Screening	11	0.7	4.9
		Enrollment	11	0.7	5.3
502	F-S	Screening	11	0.7	4.8
		Enrollment	11	0.8	4.6
503	F-S	Screening	10	0.7	2.7
		Enrollment	9	0.7	3.1
504	F-S	Screening	10	0.6	3.8
		Enrollment	13	0.6	3.8
505	F-NS	Screening	14	0.8	3.8
		Enrollment	17	0.8	4.4
506	F-S	Screening	10	0.6	4.5
		Enrollment	11	0.6	4.3

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-25
Chemistry Laboratory Data by Subject: Serum Electrolytes
(Page 1 of 12)

Subject Number	Subject Classification ^a	Timepoint	Calcium (mg/dL)	Chloride (mEq/L)	Iron (µg/dL)	Phosphorus (mg/dL)	Potassium (mEq/L)	Sodium (mEq/L)
001	F-S	Screening	9.6	106	81	3.3	4.7	142
		Enrollment	9.2	105	64	3.4	4.5	141
002	F-S	Screening	9.1	108	27 L	3.4	4.3	142
		Enrollment	9.9	105	22 L	3.2	5.0	141
003	F-S	Screening	9.7	105	66	3.6	3.9	141
		Enrollment	9.0	110	51	3.8	4.1	143
004	F-S	Screening	9.8	106	86	4.5	4.7	144
		Enrollment	9.1	105	22 L	3.9	4.1	141
005	F-S	Screening	10.3	111	90	2.7	3.8	147
		Enrollment	9.7	109	51	3.3	4.5	145
006	F-S	Screening	9.7	102	51	3.9	4.3	138
		Enrollment	9.8	104	207 H	4.0	4.7	140
007	F-S	Screening	9.6	105	112	3.8	4.0	140
		Enrollment	9.5	108	112	3.5	4.3	143
008	F-S	Screening	9.6	107	80	3.7	3.7	143
		Enrollment	9.2	109	65	3.0	4.3	142
009	F-S	Screening	10.0	105	49	4.1	4.7	142
		Enrollment	9.8	106	48	4.0	4.4	141
010	F-S	Screening	9.7	105	91	4.4	4.7	143
		Enrollment	9.4	107	254 H	3.3	4.4	141
011	F-S	Screening	9.0	109	85	3.5	4.7	142
		Enrollment	9.1	108	81	2.8	4.7	143
012	F-S	Screening	9.3	108	30	3.5	4.1	142
		Enrollment	9.6	110	58	3.4	4.5	143

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-25
Chemistry Laboratory Data by Subject: Serum Electrolytes
(Page 2 of 12)

Subject Number	Subject Classification*	Timepoint	Calcium (mg/dL)	Chloride (mEq/L)	Iron (µg/dL)	Phosphorus (mg/dL)	Potassium (mEq/L)	Sodium (mEq/L)
013	F-S	Screening	9.9	104	63	3.8	4.0	142
		Enrollment	9.3	107	105	3.2	4.3	143
014	F-S	Screening	9.4	106	161 H	Hemolysis	Hemolysis	138
		Screening (R)	9.5	107		3.1	4.6	141
		Enrollment	9.3	108	91	3.2	4.8	142
015	F-S	Screening	9.7	108	48	4.1	4.9	143
		Enrollment	9.5	107	57	4.3	4.3	141
016	F-S	Screening	9.9	106	91	3.7	4.1	142
		Enrollment	9.6	107	48	3.3	4.2	142
017	F-S	Screening	9.7	105	162 H	3.7	4.4	142
		Enrollment	9.5	107	79	2.7	4.2	141
018	F-S	Screening	9.6	106	68	4.2	4.2	141
		Enrollment	9.7	106	112	3.5	4.1	139
019	F-S	Screening	9.3	106	73	2.9	4.3	141
		Enrollment	9.4	110	75	3.0	4.3	143
020	F-S	Screening	9.4	106	79	4.1	4.1	143
		Enrollment	9.6	111	137	3.5	3.9	144
021	F-S	Screening	9.7	107	124	3.7	4.0	140
		Enrollment	9.5	111	112	3.9	4.1	143
022	F-S	Screening	9.5	106	75	4.6	4.6	138
		Enrollment	9.5	107	43	3.3	3.8	141
023	F-S	Screening	9.9	109	75	5.0	4.1	144
		Enrollment	9.3	102	72	3.9	4.3	137
024	F-S	Screening	9.2	105	75	3.3	4.5	138
		Enrollment	9.4	107	61	3.3	4.4	141

* Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-25
Chemistry Laboratory Data by Subject: Serum Electrolytes
(Page 3 of 12)

Subject Number	Subject Classification ^a	Timepoint	Calcium (mg/dL)	Chloride (mEq/L)	Iron (µg/dL)	Phosphorus (mg/dL)	Potassium (mEq/L)	Sodium (mEq/L)
025	F-S	Screening	9.6	108	33	3.9	3.8	144
		Enrollment	10.1	106	67	3.7	4.0	142
026	F-S	Screening	9.4	106	86	3.0	4.3	143
		Enrollment	9.2	107	66	3.5	4.1	142
027	F-S	Screening	9.9	103	17 L	3.6	4.7	141
		Enrollment	9.8	104	60	3.7	4.6	142
028	F-S	Screening	9.4	104	85	4.5	3.8	137
		Enrollment	9.2	110	55	3.4	4.1	141
029	F-S	Screening	10.0	105	103	3.5	4.6	140
		Enrollment	9.5	107	128	3.0	4.2	141
030	F-S	Screening	9.4	108	77	3.7	4.4	139
		Enrollment	9.1	108	53	3.4	4.0	140
031	F-S	Screening	9.4	108	61	2.7	3.8	141
		Enrollment	9.6	104	87	3.4	4.4	140
032	F-S	Screening	8.7	106	54	3.9	4.7	139
		Enrollment	8.8	108	111	3.7	4.7	142
033	F-S	Screening	9.4	105	133	2.6	3.9	142
		Enrollment	9.5	107	152	2.3	4.3	141
034	F-S	Screening	9.5	107	85	2.7	3.9	140
		Enrollment	9.5	105	115	3.8	4.3	141
035	F-S	Screening	9.2	108	121	3.4	4.4	143
		Enrollment	9.1	106	82	3.5	4.3	141
036	M-S	Screening	9.6	105	91	2.9	4.2	141
		Enrollment	9.4	105	97	2.8	4.0	143

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-25
Chemistry Laboratory Data by Subject: Serum Electrolytes
(Page 4 of 12)

Subject Number	Subject Classification ^a	Timepoint	Calcium (mg/dL)	Chloride (mEq/L)	Iron (µg/dL)	Phosphorus (mg/dL)	Potassium (mEq/L)	Sodium (mEq/L)
037	M-S	Screening	9.6	104	85	4.3	4.1	142
		Enrollment	9.3	106	74	3.4	4.2	143
038	M-S	Screening	9.8	103	52	3.7	4.2	140
		Enrollment	9.6	106	88	3.8	4.2	143
039	M-S	Screening	9.8	109	153	3.5	4.3	145
		Enrollment	10.0	105	139	3.6	4.2	141
040	M-S	Screening	9.2	108	71	3.3	3.9	143
		Enrollment	9.5	103	71	2.9	4.1	139
041	M-S	Screening	9.7	111	89	3.8	4.9	147
		Enrollment	9.6	107	87	3.5	5.2	143
042	M-S	Screening	9.5	104	107	3.8	4.2	143
		Enrollment	9.8	104	123	3.6	4.5	141
043	M-S	Screening	9.7	104	108	3.6	4.9	138
		Enrollment	9.5	111	108	4.9	4.4	147
044	M-S	Screening	9.6	100	117	4.2	4.0	136
		Enrollment	9.5	112	103	4.8	4.8	149 H
045	M-S	Screening	9.6	104	67	3.1	4.3	143
		Enrollment	9.7	109	68	3.4	3.9	146
046	M-S	Screening	9.6	105	97	4.0	4.9	141
		Enrollment	9.8	105	130	4.6	4.4	143
047	M-S	Screening	9.7	105	154	3.0	4.3	144
		Enrollment	9.7	106	187 H	3.3	4.3	142
048	M-S	Screening	9.8	104	57	4.4	4.7	141
		Enrollment	9.8	107	93	3.7	4.9	144

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.3-25
Chemistry Laboratory Data by Subject: Serum Electrolytes
(Page 5 of 12)

Subject Number	Subject Classification ^a	Timepoint	Calcium (mg/dL)	Chloride (mEq/L)	Iron (µg/dL)	Phosphorus (mg/dL)	Potassium (mEq/L)	Sodium (mEq/L)
049	M-S	Screening	9.6	105	106	4.0	4.7	142
		Enrollment	9.0	104	60	4.1	4.9	141
050	M-S	Screening	9.7	102	129	3.8	4.3	140
		Enrollment	9.4	104	77	4.2	4.4	142
051	M-S	Screening	9.8	104	142	3.8	4.3	144
		Screening (U)	9.3	106		5.4 H	3.9	141
		Enrollment	9.5	107	163 H	3.6	4.1	145
052	M-S	Screening	9.7	103	198 H	4.7	5.1	142
		Enrollment	9.5	105	222 H	4.5	4.4	142
053	M-S	Screening	9.7	105	87	3.7	4.5	136
		Enrollment	9.7	100	116	3.8	5.2	138
054	M-S	Screening	10.0	104	149	3.4	4.6	141
		Enrollment	9.1	108	126	4.2	4.4	145
055	M-S	Screening	10.1	103	94	3.7	4.4	142
		Enrollment	9.2	107	98	3.1	4.4	143
056	M-S	Screening	9.9	107	76	4.0	4.5	144
		Enrollment	9.3	104	82	3.8	4.3	141
		Enrollment (U)	10.1	104		4.3	4.6	141
057	M-S	Screening	10.3	106	121	3.7	4.4	139
		Enrollment	9.2	106	72	4.5	4.3	140
058	M-S	Screening	9.9	104	78	3.8	3.9	143
		Enrollment	9.4	107	122	3.4	3.8	145
059	M-S	Screening	9.4	104	89	4.1	4.0	143
		Enrollment	9.2	106	90	3.6	4.8	144
060	M-S	Screening	9.6	110	97	3.1	4.4	144
		Enrollment	9.2	107	103	3.2	4.5	141

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-25
Chemistry Laboratory Data by Subject: Serum Electrolytes
(Page 6 of 12)

Subject Number	Subject Classification ^a	Timepoint	Calcium (mg/dL)	Chloride (mEq/L)	Iron (µg/dL)	Phosphorus (mg/dL)	Potassium (mEq/L)	Sodium (mEq/L)
061	M-S	Screening	10.2	105	75	4.1	4.7	143
		Enrollment	10.0	105	75	4.9	4.0	144
062	M-S	Screening	9.9	104	75	3.1	4.4	142
		Enrollment	9.4	107	105	2.2	3.8	140
063	M-S	Screening	10.2	104	51	5.6 H	4.2	143
		Enrollment	9.3	106	93	3.3	4.2	142
065	M-S	Screening	9.4	105	162 H	3.6	4.3	143
		Enrollment	9.6	104	73	3.5	4.4	143
066	M-S	Screening	10.0	104	60	3.3	4.3	143
		Enrollment	9.5	101	35 L	4.4	5.1	140
067	M-S	Screening	9.9	102	195 H	2.4	4.3	139
		Enrollment	9.7	104	152	3.0	4.2	141
068	M-S	Screening	9.7	104	92	3.3	3.9	138
		Enrollment	9.4	104	37 L	3.7	4.0	141
069	M-S	Screening	10.6 H	104	106	4.6	4.4	146
		Enrollment	10.3	105	66	5.7 H	4.3	143
071	F-NS	Screening	10.0	107	68	3.9	4.3	141
		Enrollment	9.6	107	63	3.4	4.3	143
072	F-NS	Screening	9.6	106	83	3.9	4.0	140
		Enrollment	8.7	110	46	3.6	4.0	145
073	F-NS	Screening	8.9	107	82	3.6	4.4	139
		Enrollment	9.1	106	152	3.3	4.1	140
074	F-NS	Screening	9.5	105	211 H	3.4	3.9	139
		Enrollment	9.1	110	114	2.7	3.9	142

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-25
Chemistry Laboratory Data by Subject: Serum Electrolytes
(Page 7 of 12)

Subject Number	Subject Classification*	Timepoint	Calcium (mg/dL)	Chloride (mEq/L)	Iron (µg/dL)	Phosphorus (mg/dL)	Potassium (mEq/L)	Sodium (mEq/L)
075	F-NS	Screening	9.5	104	47	3.9	4.2	138
		Enrollment	8.8	109	21 L	3.5	4.2	141
076	F-NS	Screening	10.3	108	122	3.7	4.3	144
		Enrollment	9.8	110	77	3.2	4.7	144
077	F-NS	Screening	9.5	106	78	3.5	3.7	142
		Enrollment	9.4	110	60	3.5	4.2	144
078	F-NS	Screening	8.9	107	37	3.5	3.8	141
		Enrollment	9.1	109	92	3.1	4.5	142
079	F-NS	Screening	9.2	111	156	3.4	4.1	145
		Enrollment	9.2	110	140	2.5	3.7	144
080	F-NS	Screening	9.4	109	29 L	4.2	3.7	146
		Enrollment	9.3	109	38	4.2	4.1	143
081	F-NS	Screening	9.7	108	87	4.0	4.1	144
		Enrollment	9.4	109	115	3.8	4.1	143
082	F-NS	Screening	9.3	105	58	3.6	4.4	140
		Enrollment	8.8	106	70	3.2	4.2	139
083	F-NS	Screening	9.5	108	113	3.4	4.3	143
		Enrollment	9.2	109	140	3.3	3.9	145
084	F-NS	Screening	9.9	108	109	3.6	4.8	144
		Enrollment	9.7	111	70	4.1	4.9	147 H
085	F-NS	Screening	9.8	107	111	3.2	4.8	141
		Enrollment	10.1	102	119	4.0	4.2	139
086	F-NS	Screening	9.6	105	117	3.4	4.6	142
		Enrollment	9.6	108	112	3.6	4.2	143

* Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-25
Chemistry Laboratory Data by Subject: Serum Electrolytes
(Page 8 of 12)

Subject Number	Subject Classification ^a	Timepoint	Calcium (mg/dL)	Chloride (mEq/L)	Iron (µg/dL)	Phosphorus (mg/dL)	Potassium (mEq/L)	Sodium (mEq/L)
087	F-NS	Screening	9.8	105	89	3.6	4.4	142
		Enrollment	9.8	107	54	3.4	4.7	143
088	F-NS	Screening	9.7	103	117	3.2	4.1	139
		Enrollment	9.3	104	106	3.4	4.0	141
089	F-NS	Screening	9.2	108	67	4.2	4.8	142
		Enrollment	9.4	103	52	4.8	4.4	138
090	F-NS	Screening	9.8	108	58	3.5	4.2	147 H
		Enrollment	9.9	110	72	3.6	4.6	147 H
091	F-NS	Screening	9.9	106	80	4.0	4.1	139
		Enrollment	9.9	105	122	3.9	4.3	141
092	F-NS	Screening	9.4	103	50	3.6	4.2	140
		Enrollment	9.8	106	38	3.4	4.5	142
093	F-NS	Screening	9.7	104	66	4.9	4.6	142
		Enrollment	9.2	102	73	4.8	4.2	140
094	F-NS	Screening	9.5	102	89	3.5	3.7	139
		Enrollment	9.7	105	123	3.8	3.5	141
095	F-NS	Screening	10.9 H	104	105	2.9	4.5	134 L
		Enrollment	10.6 H	112	136	2.8	5.1	146 H
096	F-NS	Screening	9.9	107	74	3.0	4.2	140
		Enrollment	9.6	103	83	3.8	4.1	137
097	F-NS	Screening	9.7	105	72	3.6	5.0	139
		Enrollment	9.8	107	100	3.6	4.5	142
098	F-NS	Screening	9.8	103	187 H	3.7	3.9	139
		Enrollment	9.8	105	55	3.8	4.5	143

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-25
Chemistry Laboratory Data by Subject: Serum Electrolytes
(Page 9 of 12)

Subject Number	Subject Classification ^a	Timepoint	Calcium (mg/dL)	Chloride (mEq/L)	Iron (µg/dL)	Phosphorus (mg/dL)	Potassium (mEq/L)	Sodium (mEq/L)
099	F-NS	Screening	9.9	107	83	3.8	4.0	142
		Enrollment	9.4	106	90	4.2	4.0	143
100	F-NS	Screening	9.5	106	90	3.5	4.1	140
		Enrollment	9.1	104	87	3.4	4.9	141
101	F-NS	Screening	10.4 H	105	96	4.2	4.8	142
		Enrollment	10.0	104	41	3.9	4.1	142
102	F-NS	Screening	10.1	103	92	3.0	4.5	140
		Enrollment	9.8	106	89	3.0	4.3	138
103	F-NS	Screening	9.6	99	111	3.0	4.0	136
		Enrollment	9.7	103	68	3.6	4.5	141
104	M-NS	Screening	9.9	101	110	4.5	4.5	140
		Enrollment	9.9	105	163 H	4.6	4.8	142
105	M-NS	Screening	10.0	104	128	3.5	4.5	140
		Enrollment	9.5	103	61	3.8	4.3	140
106	M-NS	Screening	9.3	100	94	3.3	4.0	134
		Enrollment	9.3	106	87	3.2	4.1	142
107	M-NS	Screening	9.7	109	94	3.8	4.5	142
		Enrollment	9.8	107	87	3.7	4.3	143
108	M-NS	Screening	9.8	109	40 L	4.2	4.2	142
		Enrollment	8.9	110	104	3.5	4.1	143
109	M-NS	Screening	9.8	103	43 L	4.2	4.1	142
		Enrollment	9.0	106	53	3.4	4.3	141
110	M-NS	Screening	9.0	109	75	2.9	4.8	145
		Enrollment	9.2	107	89	3.7	4.5	143

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-25
Chemistry Laboratory Data by Subject: Serum Electrolytes
(Page 10 of 12)

Subject Number	Subject Classification ^a	Timepoint	Calcium (mg/dL)	Chloride (mEq/L)	Iron (µg/dL)	Phosphorus (mg/dL)	Potassium (mEq/L)	Sodium (mEq/L)
111	M-NS	Screening	9.8	104	114	3.8	4.7	144
		Enrollment	9.6	107	149	3.5	4.7	143
112	M-NS	Screening	9.4	103	68	3.1	4.8	140
		Enrollment	9.3	106	103	3.1	4.9	142
113	M-NS	Screening	9.3	103	225 H	3.8	4.2	141
		Enrollment	9.4	106	82	3.8	4.7	140
114	M-NS	Screening	9.7	106	46	3.4	3.9	144
		Enrollment	9.5	105	42 L	4.1	3.7	142
115	M-NS	Screening	10.1	106	89	3.8	5.0	142
		Enrollment	9.8	108	91	3.9	4.9	145
116	M-NS	Screening	10.2	104	89	3.9	4.1	145
		Enrollment	9.3	104	70	3.1	4.1	142
117	M-NS	Screening	9.8	104	56	3.8	4.5	145
		Enrollment	9.4	105	76	3.3	4.3	143
118	M-NS	Screening	10.1	104	72	4.7	5.6 H	142
		Enrollment	9.9	104	65	4.0	5.1	141
119	M-NS	Screening	9.5	105	109	3.5	4.1	139
		Enrollment	9.8	109	88	4.3	4.5	146
120	M-NS	Screening	9.6	111	62	3.4	4.4	151 H
		Enrollment	9.9	111	138	3.5	4.8	148 H
121	M-NS	Screening	9.6	102	91	3.2	3.7	139
		Enrollment	9.7	107	49	4.2	4.5	145
122	M-NS	Screening	10.2	103	78	4.1	4.1	143
		Enrollment	9.4	103	54	5.0	4.2	142

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-25
Chemistry Laboratory Data by Subject: Serum Electrolytes
(Page 11 of 12)

Subject Number	Subject Classification ^a	Timepoint	Calcium (mg/dL)	Chloride (mEq/L)	Iron (µg/dL)	Phosphorus (mg/dL)	Potassium (mEq/L)	Sodium (mEq/L)
123	M-NS	Screening	9.6	104	86	3.4	4.3	142
		Enrollment	8.9	106	109	2.8	4.2	142
124	M-NS	Screening	9.7	111	95	4.3	4.1	154 H
		Enrollment	9.7	104	84	4.0	3.9	141 142
125	M-NS	Screening	9.7	104	97	3.4	3.6	141
		Enrollment	9.9	109	161 H	3.0	4.0	147
126	M-NS	Screening	9.0	105	67	3.6	4.2	138
		Enrollment	8.9	106	149	3.2	4.4	142
127	M-NS	Screening	9.9	104	102	3.4	4.2	140
		Enrollment	9.5	110	116	3.6	4.2	144
128	M-NS	Screening	10.5 H	107	93	3.6	4.9	145
		Enrollment	9.5	104	101	3.2	4.3	138
129	M-NS	Screening	10.2	108	87	4.5	4.2	144
		Enrollment	9.5	106	91	3.6	4.5	143
130	M-NS	Screening	10.1	105	124	3.4	4.4	143
		Enrollment	9.4	105	79	3.3	4.1	139
131	M-NS	Screening	10.1	106	104	4.0	4.6	143
		Enrollment	9.5	107	133	3.7	4.5	142
132	M-NS	Screening	10.0	102	108	3.7	4.3	140
		Enrollment	9.7	103	113	3.4	4.7	143
133	M-NS	Screening	10.0	106	117	3.5	4.0	141
		Enrollment	9.4	107	68	3.6	3.9	144
134	M-NS	Screening	10.0	100	84	3.1	4.1	139
		Enrollment	9.9	102	117	4.7	3.9	142

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-25
Chemistry Laboratory Data by Subject: Serum Electrolytes
(Page 12 of 12)

Subject Number	Subject Classification ^a	Timepoint	Calcium (mg/dL)	Chloride (mEq/L)	Iron (µg/dL)	Phosphorus (mg/dL)	Potassium (mEq/L)	Sodium (mEq/L)
135	M-NS	Screening	9.9	102	65	3.6	4.1	143
		Enrollment	9.6	103	57	3.4	4.1	140
500	F-NS	Screening	9.4	106	133	3.4	4.1	141
		Enrollment	9.6	106	55	3.7	4.6	142
501	F-NS	Screening	9.7	108	158	3.7	3.7	141
		Enrollment	9.3	108	121	3.7	4.6	143
502	F-S	Screening	9.7	108	101	3.3	3.7	140
		Enrollment	9.6	108	154	3.4	4.1	145
503	F-S	Screening	9.4	108	68	3.5	4.1	141
		Enrollment	8.9	106	104	2.9	4.0	140
504	F-S	Screening	9.6	105	123	3.9	3.8	140
		Enrollment	9.8	106	69	4.3	4.4	139
505	F-NS	Screening	9.4	107	147	3.3	4.6	141
		Enrollment	9.4	106	163 H	3.6	4.7	141
506	F-S	Screening	9.4	105	107	4.2	3.8	140
		Enrollment	9.8	107	119	4.1	4.8	141

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-26
Hematology Laboratory Data by Subject: CBC
(Page 1 of 12)

Subject Number	Subject Classification ^a	Timepoint	Hematocrit (%)	Hemoglobin (g/dL)	RBC (x10 ⁶ /μL)	RBC Morphology	MCH (pg)	MCHC (g/dL)	MCV (fL)	Platelets (x10 ³ /μL)	WBC (x10 ³ /μL)
001	F-S	Screening Enrollment	38	12.8	4.4	Normocytic	29	34	87	443 H	12.02 H
			39	12.7	4.2	Normocytic	30	33	92	307	10.46
002	F-S	Screening Enrollment	41	13.6	5.6	Microcytic Anisocytosis	24 L	34	72 L	373	8.14
			45	13.9	5.7 H	Normocytic	24 L	31	78 L	368	11.29 H
003	F-S	Screening Enrollment	37	12.5	4.1	Normocytic	31	34	91	323	7.83
			38	12.0	4.0 L	Normocytic	30	31	97	243	6.20
004	F-S	Screening Enrollment	38	13.0	4.6	Normocytic	28	35	82	314	6.80
			38	12.6	4.4	Normocytic	29	33	86	238	10.44
005	F-S	Screening Enrollment	38	13.5	4.3	Normocytic	32	36	89	346	7.03
			40	13.0	4.2	Normocytic	31	33	95	299	5.83
006	F-S	Screening Enrollment	41	13.9	4.2	Normocytic	33	34	98	367	12.91 H
			45	14.7	4.4	Anisocytosis	33	33	102 H	355	8.32
007	F-S	Screening Enrollment	41	13.8	4.7	Normocytic	29	34	87	299	8.64
			43	13.9	4.6	Normocytic	30	32	93	199	7.88
008	F-S	Screening Enrollment	42	14.5	4.7	Normocytic	31	35	90	170	5.58
			40	13.5	4.5	Normocytic	30	33	90	171	6.14
009	F-S	Screening Enrollment	39	13.1	4.6	Normocytic	29	33	85	226	5.44
			41	13.6	4.6	Normocytic	30	33	89	254	5.55
010	F-S	Screening Enrollment	40	13.6	4.3	Normocytic	32	34	93	267	6.58
			37	12.7	3.9 L	Normocytic	33	34	96	187	5.81
011	F-S	Screening Enrollment	39	13.5	4.5	Normocytic	30	34	88	282	9.34
			39	13.2	4.3	Normocytic	31	34	90	269	8.68
012	F-S	Screening Enrollment	43	14.5	5.2	Normocytic	28	34	82	171	8.93
			44	14.7	5.2	Normocytic	28	34	84	151	8.28

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-26
Hematology Laboratory Data by Subject: CBC
(Page 2 of 12)

Subject Number	Subject Classification ^a	Timepoint	Hematocrit (%)	Hemoglobin (g/dL)	RBC ($\times 10^3/\mu\text{L}$)	RBC Morphology	MCH (pg)	MCHC (g/dL)	MCV (fL)	Platelets ($\times 10^3/\mu\text{L}$)	WBC ($\times 10^3/\mu\text{L}$)
013	F-S	Screening Enrollment	41	14.5	4.7	Normocytic	31	35	89	209	5.98
			43	15.0	4.5	Normocytic	33	35	96	164	5.74
014	F-S	Screening Enrollment	39	12.9	4.4	Normocytic	29	33	88	320	8.36
			40	12.9	4.3	Normocytic	30	32	93	325	6.93
015	F-S	Screening Enrollment	42	13.8	4.9	Normocytic	29	33	87	408 H	9.45
			42	13.8	4.6	Normocytic	30	33	90	301	7.08
016	F-S	Screening Enrollment	40	13.7	4.6	Normocytic	30	34	88	358	10.71 H
			39	12.7	4.3	Normocytic	30	33	90	378	10.12
017	F-S	Screening Enrollment	40	13.7	4.6	Normocytic	30	34	87	302	6.93
			39	13.1	4.5	Normocytic	29	34	88	320	7.35
018	F-S	Screening Enrollment	41	13.5	4.6	Normocytic	30	33	90	316	8.93
			42	13.6	4.6	Normocytic	30	33	91	249	9.45
019	F-S	Screening Enrollment	37	12.4	4.3	Normocytic	29	33	87	207	6.43
			36	12.2	4.0 L	Normocytic	31	34	90	168	7.37
020	F-S	Screening Enrollment	46	14.9	4.7	Normocytic	32	33	97	341	7.38
			45	14.7	4.6	Normocytic	32	33	98	320	7.68
021	F-S	Screening Enrollment	36	12.4	3.9 L	Normocytic	32	35	92	285	9.43
			37	12.8	3.8 L	Normocytic	34	34	98	166	5.74
022	F-S	Screening Enrollment	40	14.3	4.6	Normocytic	31	36	88	286	9.64
			41	14.0	4.7	Normocytic	30	34	89	272	9.01
023	F-S	Screening Enrollment	44	15.7	4.8	Normocytic	33	36	92	202	10.28
			43	14.7	4.6	Normocytic	32	34	93	187	10.77 H
024	F-S	Screening Enrollment	43	14.2	4.6	Normocytic	31	33	94	299	10.62
			41	14.4	4.4	Normocytic	33	35	93	252	12.13 H

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-26
Hematology Laboratory Data by Subject: CBC
(Page 3 of 12)

Subject Number	Subject Classification ^a	Timepoint	Hematocrit (%)	Hemoglobin (g/dL)	RBC (x10 ⁶ /μL)	RBC Morphology	MCH (pg)	MCHC (g/dL)	MCV (fL)	Platelets (x10 ³ /μL)	WBC (x10 ³ /μL)
025	F-S	Screening	39	13.3	4.4	Normocytic	30	34	89	372	16.26 HT
		Screening (U)	38	13.0	4.2	Normocytic	31	34	91	357	14.93 H
		Enrollment	40	13.1	4.4	Normocytic	30	33	90	342	11.23 H
026	F-S	Screening	44	15.1	4.9	Normocytic	31	35	89	242	6.81
		Enrollment	45	14.3	4.9	Normocytic	29	32	92	170	4.95
027	F-S	Screening	40	13.5	4.5	Normocytic	30	34	90	251	3.69 L
		Enrollment	43	14.1	4.7	Normocytic	30	33	91	280	9.54
028	F-S	Screening	33 L	11.4 L	3.6 L	Normocytic	31	35	90	218	11.05 H
		Enrollment	33 L	11.3 L	3.6 L	Normocytic	31	34	92	203	9.44
029	F-S	Screening	41	13.9	4.7	Normocytic	30	34	87	275	9.39
		Enrollment	41	13.8	4.6	Normocytic	30	34	88	263	7.86
030	F-S	Screening	43	14.2	4.8	Normocytic	30	33	90	262	5.88
		Enrollment	38	13.3	4.3	Normocytic	31	35	89	268	4.76
031	F-S	Screening	37	12.7	4.7	Normocytic	27	34	81	320	5.39
		Enrollment	40	13.6	4.8	Normocytic	29	34	84	258	6.22
032	F-S	Screening	42	13.8	4.8	Normocytic	29	33	87	196	7.24
		Enrollment	45	14.5	5.0	Normocytic	29	33	89	188	7.71
033	F-S	Screening	43	14.2	4.6	Normocytic	31	34	92	238	7.00
		Enrollment	43	14.2	4.5	Normocytic	32	33	96	221	11.38 H
034	F-S	Screening	40	13.6	4.3	Normocytic	31	34	93	407 H	8.52
		Enrollment	40	13.4	4.2	Normocytic	32	34	94	344	9.35
035	F-S	Screening	42	14.0	4.5	Normocytic	31	34	92	255	8.83
		Enrollment	42	14.3	4.5	Normocytic	32	34	93	223	9.11
036	M-S	Screening	45	16.5	5.3	Normocytic	31	37	85	286	6.37
		Enrollment	48	15.9	5.4	Normocytic	30	33	89	260	6.03

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-26
Hematology Laboratory Data by Subject: CBC
(Page 4 of 12)

Subject Number	Subject Classification ^a	Timepoint	Hematocrit (%)	Hemoglobin (g/dL)	RBC (x10 ⁶ /μL)	RBC Morphology	MCH (pg)	MCHC (g/dL)	MCV (fL)	Platelets (x10 ³ /μL)	WBC (x10 ³ /μL)
037	M-S	Screening	44	16.0	5.1	Normocytic	32	36	87	210	5.49
		Enrollment	43	14.6	4.7	Normocytic	31	34	91	166	3.92
038	M-S	Screening	46	15.9	5.5	Normocytic	29	35	83	177	5.21
		Enrollment	43	14.6	5.2	Normocytic	28	34	84	153	5.39
039	M-S	Screening	49	16.8	5.1	Normocytic	33	34	97 H	241	9.08
		Enrollment	51	17.3	5.1	Anisocytosis	34	34	101 H	225	8.95
040	M-S	Screening	40	13.8	4.8	Normocytic	29	35	83	279	9.78
		Enrollment	41	14.1	4.9	Normocytic	29	34	84	233	7.32
041	M-S	Screening	39	12.9	4.5	Normocytic	29	33	85	282	6.86
		Enrollment	43	14.4	4.9	Normocytic	29	34	86	266	9.84
042	M-S	Screening	49	17.7	5.7	Normocytic	31	36	87	188	7.59
		Enrollment	49	17.1	5.6	Normocytic	31	35	88	177	5.45
043	M-S	Screening	46	16.1	5.5	Normocytic	29	35	85	226	10.28
		Enrollment	47	15.9	5.4	Normocytic	30	34	87	211	11.51 H
044	M-S	Screening	49	16.1	5.3	Normocytic	30	33	92	226	6.41
		Enrollment	44	14.7	4.6	Normocytic	32	34	95	162	5.35
045	M-S	Screening	49	16.8	5.3	Normocytic	32	34	93	306	4.99
		Enrollment	46	15.9	4.8	Normocytic	33	35	96	191	4.47
046	M-S	Screening	43	15.5	4.6	Normocytic	34	36	94	288	7.12
		Enrollment	44	15.4	4.7	Normocytic	33	35	95	312	7.76
047	M-S	Screening	48	15.7	5.5	Normocytic	29	33	86	216	7.06
		Enrollment	43	15.1	5.1	Normocytic	30	35	85	189	5.02
048	M-S	Screening	42	15.1	5.2	Normocytic	29	36	80	224	6.67
		Enrollment	44	14.8	5.1	Normocytic	29	34	86	164	5.36

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-26
Hematology Laboratory Data by Subject: CBC
(Page 5 of 12)

Subject Number	Subject Classification*	Timepoint	Hematocrit (%)	Hemoglobin (g/dL)	RBC ($\times 10^9/\mu\text{L}$)	RBC Morphology	MCH (pg)	MCHC (g/dL)	MCV (fL)	Platelets ($\times 10^3/\mu\text{L}$)	WBC ($\times 10^3/\mu\text{L}$)
049	M-S	Screening Enrollment	45	15.1	4.7	Normocytic	32	34	94	323	7.59
			47	15.2	4.8	Normocytic	32	32	98	282	6.11
050	M-S	Screening Enrollment	49	16.1	5.6	Normocytic	29	33	86	254	5.12
			46	15.3	5.3	Normocytic	29	33	88	306	6.10
051	M-S	Screening Enrollment	46	16.5	5.3	Normocytic	31	36	87	216	5.86
			45	16.3	5.0	Normocytic	33	36	90	178	4.20
052	M-S	Screening Enrollment	45	16.0	4.9	Normocytic	32	35	92	231	5.39
			43	15.3	4.7	Normocytic	33	36	93	203	5.02
053	M-S	Screening Enrollment	41	14.5	4.6	Normocytic	32	35	91	321	6.45
			44	14.7	4.6	Normocytic	32	34	96	360	8.89
054	M-S	Screening Enrollment	45	15.6	5.1	Normocytic	31	35	88	203	7.03
			45	15.2	4.9	Normocytic	31	34	91	184	7.54
055	M-S	Screening Enrollment	44	15.5	4.7	Normocytic	33	35	94	260	8.15
			42	14.6	4.4 L	Normocytic	33	35	96	213	7.57
056	M-S	Screening Enrollment	40	13.2	4.4 L	Normocytic	30	33	93	238	8.87
			39	13.5	4.3 L	Normocytic	31	34	92	255	7.72
057	M-S	Screening Enrollment	50	17.1	6.0	Normocytic	29	34	83	235	7.95
			48	17.1	5.8	Normocytic	29	36	83	200	7.83
058	M-S	Screening Enrollment	45	14.8	5.1	Normocytic	29	33	88	215	6.35
			44	15.0	5.1	Normocytic	30	34	87	175	5.11
059	M-S	Screening Enrollment	46	15.9	5.1	Normocytic	31	35	91	243	6.01
			45	15.4	4.9	Normocytic	32	34	92	211	5.05
060	M-S	Screening Enrollment	47	16.4	5.4	Normocytic	31	35	88	184	6.54
			47	16.4	5.4	Normocytic	30	35	87	172	6.61

* Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-26
Hematology Laboratory Data by Subject: CBC
(Page 6 of 12)

Subject Number	Subject Classification ^a	Timepoint	Hematocrit (%)	Hemoglobin (g/dL)	RBC (x10 ⁶ /μL)	RBC Morphology	MCH (pg)	MCHC (g/dL)	MCV (fL)	Platelets (x10 ³ /μL)	WBC (x10 ³ /μL)
061	M-S	Screening	49	16.8	5.7	Normocytic	29	34	86	200	7.98
		Enrollment	47	16.1	5.4	Normocytic	30	34	87	154	7.50
062	M-S	Screening	47	16.5	5.4	Normocytic	31	35	87	303	12.51 H
		Enrollment	44	16.2	5.1	Normocytic	32	37	86	283	9.99
063	M-S	Screening	45	15.9	5.2	Normocytic	31	36	87	171	7.85
		Enrollment	43	15.3	5.0	Normocytic	31	35	87	157	6.36
065	M-S	Screening	45	15.4	5.3	Normocytic	29	34	85	267	4.59
		Enrollment	43	15.1	5.1	Normocytic	30	35	84	251	6.08
066	M-S	Screening	43	13.9	5.3	Normocytic	26	32	82	346	10.72 H
		Enrollment	42	13.9	5.1	Normocytic	27	33	82	314	10.37
067	M-S	Screening	51	16.8	5.7	Normocytic	30	33	89	311	6.41
		Enrollment	48	16.6	5.6	Normocytic	30	35	86	265	6.38
068	M-S	Screening	40	14.1	4.6	Normocytic	31	35	88	230	9.76
		Enrollment	39	13.3	4.5	Normocytic	30	34	87	320	10.46
069	M-S	Screening	46	15.5	5.5	Normocytic	28	34	84	329	10.51
		Enrollment	46	15.6	5.3	Normocytic	29	34	87	253	11.71 H
071	F-NS	Screening	41	14.1	4.9	Normocytic	29	34	85	331	6.67
		Enrollment	43	13.5	4.9	Normocytic	28	31	89	301	5.25
072	F-NS	Screening	38	13.6	4.4	Normocytic	31	36	87	219	5.00
		Enrollment	35	12.1	3.9 L	Normocytic	31	35	90	165	3.13 L
073	F-NS	Screening	38	13.1	4.6	Normocytic	29	34	84	277	6.89
		Enrollment	39	12.7	4.5	Normocytic	28	33	86	264	6.07
074	F-NS	Screening	41	14.3	4.6	Normocytic	31	35	90	324	10.11
		Enrollment	39	12.5	4.2	Normocytic	30	32	92	239	8.18

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-26
Hematology Laboratory Data by Subject: CBC
(Page 7 of 12)

Subject Number	Subject Classification ^a	Timepoint	Hematocrit (%)	Hemoglobin (g/dL)	RBC (x10 ⁶ /μL)	RBC Morphology	MCH (pg)	MCHC (g/dL)	MCV (fL)	Platelets (x10 ³ /μL)	WBC (x10 ³ /μL)
075	F-NS	Screening	36	12.1	4.4	Normocytic	28	34	82	281	4.47
		Enrollment	37	12.1	4.5	Normocytic	27	32	84	216	4.96
076	F-NS	Screening	44	14.6	5.0	Normocytic	29	34	87	304	9.72
		Enrollment	43	14.1	4.7	Normocytic	30	33	92	225	10.07
077	F-NS	Screening	40	13.8	4.3	Normocytic	33	34	94	265	9.57
		Enrollment	40	13.8	4.2	Normocytic	33	34	97	241	5.52
078	F-NS	Screening	37	12.5	4.1	Normocytic	30	34	91	287	4.65
		Enrollment	39	12.9	4.2	Normocytic	31	33	93	262	3.37 L
079	F-NS	Screening	40	13.0	4.5	Normocytic	29	33	89	292	7.62
		Enrollment	41	13.7	4.4	Normocytic	31	34	93	315	6.22
080	F-NS	Screening	37	11.7	4.6	Normocytic	26	32	80	415 H	7.24
		Enrollment	37	11.8	4.5	Normocytic	26	32	82	348	6.72
081	F-NS	Screening	35	12.2	3.9 L	Normocytic	31	36	88	317	4.29
		Enrollment	33 L	11.7	3.7 L	Normocytic	31	35	90	299	4.20
082	F-NS	Screening	37	12.0	4.2	Normocytic	28	33	87	248	5.10
		Enrollment	35	11.3 L	3.9 L	Normocytic	29	32	89	183	4.13
083	F-NS	Screening	41	13.9	4.5	Normocytic	31	34	91	178	6.76
		Enrollment	41	13.5	4.3	Normocytic	31	33	95	204	7.65
084	F-NS	Screening	41	14.1	4.5	Normocytic	31	35	90	166	4.39
		Enrollment	40	13.1	4.2	Normocytic	31	33	94	153	4.14
085	F-NS	Screening	39	13.6	4.5	Normocytic	30	35	86	233	6.56
		Enrollment	44	14.1	4.9	Normocytic	29	32	90	170	6.96
086	F-NS	Screening	42	13.9	4.9	Normocytic	29	33	87	349	7.55
		Enrollment	42	13.6	4.7	Normocytic	29	33	90	290	5.05

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-26
Hematology Laboratory Data by Subject: CBC
(Page 8 of 12)

Subject Number	Subject Classification ^a	Timepoint	Hematocrit (%)	Hemoglobin (g/dL)	RBC (x10 ⁶ /μL)	RBC Morphology	MCH (pg)	MCHC (g/dL)	MCV (fL)	Platelets (x10 ³ /μL)	WBC (x10 ³ /μL)
087	F-NS	Screening	42	14.2	4.6	Normocytic	31	34	91	344	7.40
		Enrollment	41	13.8	4.4	Normocytic	31	34	92	334	5.57
088	F-NS	Screening	40	13.6	4.4	Normocytic	31	34	89	248	4.79
		Enrollment	38	13.3	4.2	Normocytic	31	35	90	189	4.23
089	F-NS	Screening	40	13.4	4.4	Normocytic	31	34	91	298	6.49
		Enrollment	36	12.7	4.1	Normocytic	31	35	89	247	5.02
090	F-NS	Screening	41	13.7	4.8	Normocytic	29	33	86	306	7.08
		Enrollment	41	14.7	4.6	Normocytic	32	36	89	273	6.33
091	F-NS	Screening	39	13.4	4.1	Normocytic	33	35	95	291	6.26
		Enrollment	41	13.9	4.3	Normocytic	33	34	97	250	6.46
092	F-NS	Screening	41	12.8	4.6	Normocytic	28	32	88	209	5.03
		Enrollment	40	13.0	4.5	Normocytic	29	33	89	206	5.92
093	F-NS	Screening	42	13.6	4.6	Normocytic	30	32	92	281	4.25
		Enrollment	39	13.2	4.3	Normocytic	31	34	91	259	4.66
094	F-NS	Screening	40	14.1	4.9	Normocytic	29	35	83	194	4.31
		Enrollment	41	13.9	4.7	Normocytic	30	34	86	285	7.54
095	F-NS	Screening	45	15.0	4.9	Normocytic	30	33	91	317	6.66
		Enrollment	43	14.1	4.6	Normocytic	31	33	94	248	5.94
096	F-NS	Screening	36	12.3	4.5	Normocytic	28	34	82	283	7.19
		Enrollment	35	12.2	4.1	Normocytic	30	35	84	216	6.79
097	F-NS	Screening	40	13.6	5.1	Normocytic	27	34	79	282	8.31
		Enrollment	38	12.6	4.6	Normocytic	28	33	83	207	8.04
098	F-NS	Screening	44	14.5	4.6	Normocytic	32	33	96	159	5.07
		Enrollment	40	13.6	4.2	Normocytic	33	34	95	178	6.10

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-26
Hematology Laboratory Data by Subject: CBC
(Page 9 of 12)

Subject Number	Subject Classification ^a	Timepoint	Hematocrit (%)	Hemoglobin (g/dL)	RBC (x10 ⁶ /μL)	RBC Morphology	MCH (pg)	MCHC (g/dL)	MCV (fL)	Platelets (x10 ³ /μL)	WBC (x10 ³ /μL)
099	F-NS	Screening	42	13.7	4.6	Normocytic	30	33	90	327	7.42
		Enrollment	44	14.3	4.8	Normocytic	30	32	92	305	5.70
100	F-NS	Screening	42	14.4	4.5	Normocytic	32	35	92	263	5.57
		Enrollment	43	14.2	4.6	Normocytic	31	33	93	253	5.72
101	F-NS	Screening	40	13.7	4.7	Normocytic	29	34	86	318	8.32
		Enrollment	41	13.4	4.6	Normocytic	29	33	88	284	9.69
102	F-NS	Screening	43	14.7	4.6	Normocytic	32	34	93	314	6.93
		Enrollment	40	13.3	4.2	Normocytic	32	34	95	266	5.95
103	F-NS	Screening	41	13.9	4.8	Normocytic	29	34	86	371	7.31
		Enrollment	41	14.0	4.7	Normocytic	30	35	87	255	6.87
104	M-NS	Screening	43	14.7	4.6	Normocytic	32	34	93	246	5.38
		Enrollment	44	14.9	4.6	Normocytic	32	34	95	217	6.33
105	M-NS	Screening	41	14.4	5.0	Normocytic	29	35	82	235	5.08
		Enrollment	45	15.2	5.3	Normocytic	29	34	85	221	4.91
106	M-NS	Screening	41	14.6	4.7	Normocytic	31	36	87	242	6.35
		Enrollment	42	14.8	4.7	Normocytic	32	36	89	219	6.00
107	M-NS	Screening	42	15.4	5.2	Normocytic	29	36	81	216	5.71
		Enrollment	45	15.3	5.3	Normocytic	29	34	84	225	5.09
108	M-NS	Screening	41	14.8	4.6	Normocytic	32	37	88	397	7.95
		Enrollment	42	14.3	4.5	Normocytic	32	34	93	359	7.53
109	M-NS	Screening	45	15.9	5.3	Normocytic	30	35	85	293	9.83
		Enrollment	44	15.1	5.0	Normocytic	30	34	89	285	5.81
110	M-NS	Screening	41	14.3	4.9	Normocytic	29	35	85	254	6.08
		Enrollment	45	14.8	5.1	Normocytic	29	33	88	193	6.21

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-26
Hematology Laboratory Data by Subject: CBC
(Page 10 of 12)

Subject Number	Subject Classification ^a	Timepoint	Hematocrit (%)	Hemoglobin (g/dL)	RBC (x10 ⁶ /μL)	RBC Morphology	MCH (pg)	MCHC (g/dL)	MCV (fL)	Platelets (x10 ³ /μL)	WBC (x10 ³ /μL)
111	M-NS	Screening	44	15.1	5.0	Normocytic	30	34	88	187	9.86
		Enrollment	47	15.6	5.1	Normocytic	31	33	93	146	4.91
112	M-NS	Screening	45	14.9	5.1	Normocytic	29	33	88	217	7.29
		Enrollment	44	15.0	4.8	Normocytic	31	34	92	192	4.95
113	M-NS	Screening	43	14.3	4.8	Normocytic	30	33	89	304	5.38
		Enrollment	46	14.7	5.1	Normocytic	29	32	90	264	4.50
114	M-NS	Screening	41	13.8	5.1	Normocytic	27	34	81	189	4.05
		Enrollment	40	13.4	4.7	Normocytic	28	34	84	176	4.61
115	M-NS	Screening	48	16.3	5.5	Normocytic	30	34	87	218	5.79
		Enrollment	52	16.6	5.7	Normocytic	29	32	91	219	6.94
116	M-NS	Screening	40	14.6	5.1	Normocytic	29	36	80	298	6.75
		Enrollment	40	13.8	4.9	Normocytic	28	34	83	222	4.08
117	M-NS	Screening	47	16.6	5.5	Normocytic	30	35	85	276	7.27
		Enrollment	46	16.4	5.4	Normocytic	30	35	86	251	4.90
118	M-NS	Screening	43	14.2	4.6	Normocytic	31	33	92	283	7.32
		Enrollment	41	13.6	4.4 L	Normocytic	31	33	94	251	5.93
119	M-NS	Screening	46	15.4	5.4	Normocytic	29	34	85	257	4.83
		Enrollment	45	15.8	5.2	Normocytic	30	35	87	223	4.98
120	M-NS	Screening	45	15.9	5.3	Normocytic	30	35	85	145	4.64
		Enrollment	46	15.4	5.2	Normocytic	29	34	87	145	4.16
121	M-NS	Screening	42	14.3	4.6	Normocytic	31	34	90	349	5.15
		Enrollment	44	14.3	4.7	Normocytic	30	33	92	338	6.48
122	M-NS	Screening	45	15.8	5.2	Normocytic	30	35	86	186	4.98
		Enrollment	43	15.2	4.8	Normocytic	32	35	90	193	5.98

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-26
Hematology Laboratory Data by Subject: CBC
(Page 11 of 12)

Subject Number	Subject Classification ^a	Timepoint	Hematocrit (%)	Hemoglobin (g/dL)	RBC (x10 ⁹ /μL)	RBC Morphology	MCH (pg)	MCHC (g/dL)	MCV (fL)	Platelets (x10 ⁹ /μL)	WBC (x10 ³ /μL)
123	M-NS	Screening	40	14.1	4.5	Normocytic	31	35	88	198	5.50
		Enrollment	40	13.7	4.3	Normocytic	32	34	92	171	4.78
124	M-NS	Screening	45	15.5	5.1	Normocytic	31	34	89	197	5.35
		Enrollment	43	14.7	4.7	Normocytic	31	34	92	206	5.33
125	M-NS	Screening	45	16.0	5.5	Normocytic	30	36	83	215	10.19
		Enrollment	46	16.5	5.3	Normocytic	31	36	88	187	7.37
126	M-NS	Screening	44	15.0	4.9	Normocytic	30	34	89	220	8.02
		Enrollment	43	14.9	4.7	Normocytic	32	34	92	189	6.11
127	M-NS	Screening	46	15.1	5.3	Normocytic	29	33	87	276	6.65
		Enrollment	42	14.2	4.7	Normocytic	30	34	88	240	5.94
128	M-NS	Screening	44	14.5	4.7	Normocytic	31	33	95	343	5.62
		Enrollment	44	14.5	4.5	Normocytic	32	33	98 H	323	5.73
129	M-NS	Screening	41	15.0	5.0	Normocytic	30	37	81	306	8.35
		Enrollment	42	14.7	5.0	Normocytic	29	35	83	276	8.81
130	M-NS	Screening	44	14.9	4.9	Normocytic	30	34	89	236	7.54
		Enrollment	42	14.4	4.5	Normocytic	32	34	93	195	6.63
131	M-NS	Screening	49	17.0	5.4	Normocytic	32	35	90	227	5.65
		Enrollment	49	16.3	5.3	Normocytic	31	34	91	244	4.01
132	M-NS	Screening	44	15.1	5.0	Normocytic	30	34	88	240	4.80
		Enrollment	43	15.3	4.8	Normocytic	32	35	90	207	5.07
133	M-NS	Screening	39	14.0	4.4 L	Normocytic	32	36	88	175	4.08
		Enrollment	39	13.8	4.5	Normocytic	31	35	88	169	4.63
134	M-NS	Screening	45	15.3	4.8	Normocytic	32	34	96	206	3.58 L
		Enrollment	44	15.5	4.6	Normocytic	34	35	96	231	5.77

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-26
Hematology Laboratory Data by Subject: CBC
(Page 12 of 12)

Subject Number	Subject Classification ^a	Timepoint	Hematocrit (%)	Hemoglobin (g/dL)	RBC (x10 ⁹ /μL)	RBC Morphology	MCH (pg)	MCHC (g/dL)	MCV (fL)	Platelets (x10 ³ /μL)	WBC (x10 ³ /μL)
135	M-NS	Screening	44	14.7	5.5	Normocytic	27	33	81	217	5.40
		Enrollment	43	14.5	5.4	Normocytic	27	34	80	202	5.61
500	F-NS	Screening	41	13.7	4.9	Normocytic	28	34	84	364	5.66
		Enrollment	41	14.0	4.7	Normocytic	30	34	87	301	5.64
501	F-NS	Screening	40	13.6	4.6	Normocytic	29	34	87	264	8.02
		Enrollment	40	13.6	4.6	Normocytic	30	34	87	268	6.16
502	F-S	Screening	41	14.1	4.4	Normocytic	32	34	94	281	11.50 H
		Enrollment	42	14.5	4.4	Normocytic	33	35	95	251	8.97
503	F-S	Screening	40	13.5	4.3	Normocytic	31	34	91	284	8.71
		Enrollment	41	13.6	4.6	Normocytic	30	33	91	271	12.08 H
504	F-S	Screening	42	14.2	4.3	Normocytic	33	34	97	331	9.46
		Enrollment	41	13.9	4.3	Normocytic	33	34	97	320	10.43
505	F-NS	Screening	38	12.7	4.5	Normocytic	29	33	86	249	7.19
		Enrollment	42	13.9	4.9	Normocytic	28	33	86	270	7.06
506	F-S	Screening	41	13.8	4.7	Normocytic	30	34	88	253	7.23
		Enrollment	39	13.9	4.5	Normocytic	31	35	87	210	8.15

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-27
Hematology Laboratory Data by Subject: Differential Counts
(Page 1 of 12)

Subject Number	Subject Classification ^a	Timepoint	BASO Abs (x10 ³ /μL)	BASO % (%)	EOS Abs (x10 ³ /μL)	EOS % (%)	LYMPH Abs (x10 ³ /μL)	LYMPH % (%)	MONO Abs (x10 ³ /μL)	MONO % (%)	NEUT Abs (x10 ³ /μL)	NEUT % (%)
001	F-S	Screening	0.05	0.4	0.08	0.7	3.09	25.8	0.42	3.5	8.37 H	69.7
		Enrollment	0.00	0.0	0.10	1.0	3.45	33.0	0.63	6.0	6.17	59.0
002	F-S	Screening	0.06	0.7	0.16	1.9	1.93	23.6	0.43	5.3	5.57	68.4
		Enrollment	0.07	0.6	0.20	1.8	1.90	16.9	0.47	4.2	8.63 H	76.5 H
003	F-S	Screening	0.06	0.8	0.10	1.2	1.82	23.4	0.36	4.6	5.49	70.1
		Enrollment	0.04	0.6	0.10	1.6	1.71	27.5	0.35	5.7	4.01	64.7
004	F-S	Screening	0.08	1.1	0.10	1.5	2.40	35.2	0.33	4.8	3.91	57.4
		Enrollment	0.06	0.6	0.11	1.1	1.36	13.0 L	0.47	4.5	8.43 H	80.8 H
005	F-S	Screening	0.03	0.5	0.13	1.8	2.31	33.0	0.37	5.2	4.19	59.6
		Enrollment	0.05	0.9	0.16	2.7	1.79	30.8	0.29	5.0	3.52	60.5
006	F-S	Screening	0.07	0.5	0.22	1.7	3.75	29.0	0.48	3.7	8.39 H	65.0
		Enrollment	0.04	0.5	0.18	2.2	3.37	40.6	0.40	4.8	4.32	51.9
007	F-S	Screening	0.03	0.4	0.16	1.8	3.01	34.9	0.34	3.9	5.10	59.1
		Enrollment	0.04	0.5	0.10	1.3	2.29	29.0	0.38	4.8	5.07	64.3
008	F-S	Screening	0.03	0.5	0.07	1.3	1.78	32.0	0.20	3.6	3.50	62.7
		Enrollment	0.04	0.6	0.08	1.4	1.80	29.3	0.29	4.7	3.94	64.1
009	F-S	Screening	0.05	0.8	0.12	2.2	1.91	35.1	0.35	6.5	3.01	55.4
		Enrollment	0.04	0.8	0.13	2.3	1.37	24.8	0.28	5.1	3.73	67.2
010	F-S	Screening	0.06	0.9	0.16	2.4	1.92	29.1	0.27	4.0	4.19	63.6
		Enrollment	0.06	1.1	0.23	3.9	1.91	32.7	0.41	7.0	3.21	55.3
011	F-S	Screening	0.07	0.8	0.19	2.0	2.96	31.8	0.48	5.1	5.64	60.3
		Enrollment	0.06	0.7	0.14	1.7	1.85	21.4	0.48	5.5	6.14	70.8
012	F-S	Screening	0.05	0.6	0.11	1.2	1.96	22.0	0.23	2.6	6.58	73.7
		Enrollment	0.07	0.9	0.10	1.2	1.75	21.1	0.31	3.8	6.05	73.1

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-27
Hematology Laboratory Data by Subject: Differential Counts
(Page 2 of 12)

Subject Number	Subject Classification ^a	Timepoint	BASO Abs (x10 ³ /μL)	BASO % (%)	EOS Abs (x10 ³ /μL)	EOS % (%)	LYMPH Abs (x10 ³ /μL)	LYMPH % (%)	MONO Abs (x10 ³ /μL)	MONO % (%)	NEUT Abs (x10 ³ /μL)	NEUT % (%)
013	F-S	Screening	0.04	0.7	0.09	1.5	1.35	22.6	0.21	3.6	4.28	71.6
		Enrollment	0.03	0.5	0.08	1.4	1.24	21.5	0.30	5.3	4.10	71.3
014	F-S	Screening	0.03	0.3	0.07	0.9	1.18	14.2 L	0.43	5.1	6.65	79.6 H
		Enrollment	0.02	0.3	0.09	1.4	1.53	21.9	0.38	5.5	4.91	70.8
015	F-S	Screening	0.05	0.6	0.23	2.5	2.35	24.8	0.52	5.4	6.31	66.7
		Enrollment	0.05	0.7	0.20	2.9	2.04	28.9	0.47	6.7	4.31	60.9
016	F-S	Screening	0.10	1.0	0.20	1.9	2.49	23.3	0.39	3.7	7.52 H	70.2
		Enrollment	0.08	0.8	0.20	1.9	2.15	21.3	0.38	3.7	7.31 H	72.3
017	F-S	Screening	0.06	0.9	0.08	1.2	1.78	25.7	0.39	5.6	4.61	66.6
		Enrollment	0.05	0.6	0.08	1.1	2.03	27.6	0.36	4.9	4.83	65.7
018	F-S	Screening	0.05	0.5	0.17	1.9	2.17	24.3	0.41	4.6	6.14	68.7
		Enrollment	0.04	0.4	0.17	1.8	1.86	19.6	0.49	5.2	6.89	72.9
019	F-S	Screening	0.04	0.6	0.11	1.6	2.38	37.0	0.31	4.8	3.61	56.0
		Enrollment	0.06	0.8	0.11	1.5	2.45	33.2	0.37	5.0	4.39	59.5
020	F-S	Screening	0.04	0.6	0.04	0.5	1.41	19.1	0.50	6.7	5.40	73.1
		Enrollment	0.00	0.0	0.08	1.0	1.08	14.0 L	0.31	4.0	6.22	81.0 H
021	F-S	Screening	0.06	0.6	0.29	3.1	2.42	25.6	0.36	3.9	6.31	66.8
		Enrollment	0.05	0.9	0.28	4.8	2.10	36.6	0.43	7.5	2.88	50.2
022	F-S	Screening	0.07	0.7	0.13	1.3	2.71	28.1	0.35	3.6	6.39	66.2
		Enrollment	0.05	0.5	0.08	0.9	3.10	34.5	0.41	4.5	5.37	59.6
023	F-S	Screening	0.05	0.5	0.20	1.9	2.55	24.9	0.45	4.4	7.02	68.3
		Enrollment	0.07	0.6	0.16	1.5	1.98	18.4	0.42	3.9	8.14 H	75.6 H
024	F-S	Screening	0.12	1.2	0.39	3.6	3.39	31.9	0.34	3.2	6.38	60.1
		Enrollment	0.08	0.7	0.37	3.0	2.66	22.0	0.34	2.8	8.67 H	71.5

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-27
Hematology Laboratory Data by Subject: Differential Counts
(Page 3 of 12)

Subject Number	Subject Classification ^a	Timepoint	BASO Abs (x10 ⁹ /μL)	BASO % (%)	EOS Abs (x10 ⁹ /μL)	EOS % (%)	LYMPH Abs (x10 ⁹ /μL)	LYMPH % (%)	MONO Abs (x10 ⁹ /μL)	MONO % (%)	NEUT Abs (x10 ⁹ /μL)	NEUT % (%)
025	F-S	Screening	0.11	0.7	0.87 H	5.3	5.40 H	33.2	0.35	2.2 L	9.54 H	58.6
		Screening (U)	0.07	0.4	1.10 H	7.4 H	5.21 H	34.9	0.36	2.4 L	8.19 H	54.9
		Enrollment	0.05	0.5	0.94 H	8.4 H	3.57	31.8	0.30	2.7	6.36	56.7
026	F-S	Screening	0.06	0.9	0.11	1.6	1.33	19.5	0.28	4.2	5.03	73.9
		Enrollment	0.03	0.7	0.11	2.2	1.16	23.6	0.31	6.2	3.33	67.3
027	F-S	Screening	0.03	0.8	0.03	0.8	0.93	25.2	0.18	4.8	2.52	68.4
		Enrollment	0.06	0.6	0.05	0.6	2.26	23.6	0.42	4.4	6.76	70.8
028	F-S	Screening	0.17	1.6	0.05	0.5	3.27	29.5	0.71	6.4	6.85	62.0
		Enrollment	0.06	0.7	0.01	0.2	2.23	23.7	1.12 H	11.8 H	6.01	63.7
029	F-S	Screening	0.03	0.3	0.13	1.4	2.75	29.3	0.45	4.8	6.02	64.2
		Enrollment	0.04	0.5	0.19	2.4	2.30	29.3	0.40	5.1	4.93	62.7
030	F-S	Screening	0.04	0.7	0.11	1.9	2.37	40.2	0.29	5.0	3.07	52.1
		Enrollment	0.04	0.8	0.11	2.2	2.12	44.5	0.28	5.8	2.22	46.6
031	F-S	Screening	0.03	0.5	0.06	1.1	1.73	32.1	0.27	5.0	3.30	61.3
		Enrollment	0.03	0.5	0.07	1.1	2.04	32.8	0.26	4.1	3.83	61.5
032	F-S	Screening	0.05	0.6	0.10	1.4	2.52	34.8	0.25	3.4	4.32	59.7
		Enrollment	0.06	0.7	0.16	2.1	2.19	28.4	0.21	2.7	5.09	66.1
033	F-S	Screening	0.07	1.0	0.12	1.8	1.87	26.7	0.31	4.4	4.62	66.1
		Enrollment	0.04	0.3	0.13	1.1	1.31	11.5 L	0.44	3.8	9.46 H	83.2 H
034	F-S	Screening	0.09	1.1	0.11	1.3	2.29	26.9	0.55	6.5	5.47	64.2
		Enrollment	0.09	0.9	0.11	1.2	2.52	27.0	0.85	9.1	5.78	61.8
035	F-S	Screening	0.03	0.4	0.10	1.2	2.75	31.1	0.34	3.9	5.61	63.5
		Enrollment	0.03	0.4	0.20	2.1	2.76	30.3	0.38	4.2	5.74	63.0
036	M-S	Screening	0.04	0.7	0.10	1.5	1.61	25.4	0.35	5.4	4.27	67.0
		Enrollment	0.05	0.8	0.17	2.8	1.62	26.9	0.34	5.6	3.87	64.1

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-27
Hematology Laboratory Data by Subject: Differential Counts
(Page 4 of 12)

Subject Number	Subject Classification ^a	Timepoint	BASO Abs (x10 ³ /μL)	BASO % (%)	EOS Abs (x10 ³ /μL)	EOS % (%)	LYMPH Abs (x10 ³ /μL)	LYMPH % (%)	MONO Abs (x10 ³ /μL)	MONO % (%)	NEUT Abs (x10 ³ /μL)	NEUT % (%)
037	M-S	Screening	0.03	0.6	0.13	2.4	2.20	39.9	0.31	5.6	2.83	51.5
		Enrollment	0.02	0.6	0.09	2.2	1.63	41.6	0.38	9.6	1.80 L	46.0
038	M-S	Screening	0.04	0.7	0.06	1.2	1.61	30.8	0.39	7.4	3.12	59.9
		Enrollment	0.04	0.7	0.13	2.4	1.47	27.3	0.38	7.0	3.37	62.6
039	M-S	Screening	0.10	1.1	0.12	1.3	2.82	31.1	0.53	5.8	5.51	60.7
		Enrollment	0.00	0.0	0.09	1.0	2.86	32.0	0.54	6.0	5.46	61.0
040	M-S	Screening	0.07	0.7	0.16	1.7	2.18	22.4	0.40	4.1	6.96	71.2
		Enrollment	0.08	1.0	0.15	2.0	1.86	25.4	0.37	5.1	4.86	66.4
041	M-S	Screening	0.18	2.6 H	0.40	5.9	2.01	29.3	0.47	6.8	3.79	55.3
		Enrollment	0.22 H	2.2 H	0.34	3.5	1.96	19.9	0.46	4.7	6.86	69.8
042	M-S	Screening	0.08	1.0	0.15	1.9	1.49	19.6	0.33	4.3	5.55	73.2
		Enrollment	0.07	1.3	0.11	2.0	1.47	27.0	0.36	6.6	3.43	63.0
043	M-S	Screening	0.11	1.1	0.14	1.3	3.44	33.4	0.94 H	9.1	5.65	55.0
		Enrollment	0.00	0.0	0.58 H	5.0	5.41 H	47.0	0.35	3.0	5.18	45.0
044	M-S	Screening	0.04	0.6	0.08	1.3	2.27	35.4	0.39	6.1	3.63	56.6
		Enrollment	0.03	0.5	0.10	1.8	2.61	48.8 H	0.36	6.8	2.25	42.0
045	M-S	Screening	0.07	1.3	0.02	0.5	1.02	20.6	0.35	7.1	3.52	70.6
		Enrollment	0.03	0.8	0.07	1.7	1.00	22.3	0.48	10.8 H	2.89	64.5
046	M-S	Screening	0.03	0.5	0.14	2.0	2.74	38.7	0.43	6.0	3.76	52.9
		Enrollment	0.05	0.7	0.13	1.6	3.14	40.5	0.48	6.2	3.95	50.9
047	M-S	Screening	0.09	1.3	0.08	1.2	2.01	28.4	0.52	7.4	4.36	61.8
		Enrollment	0.00	0.0	0.05	1.0	1.91	38.0	0.40	8.0	2.66	53.0
048	M-S	Screening	0.05	0.7	0.08	1.2	2.08	31.2	0.43	6.5	4.03	60.4
		Enrollment	0.06	1.1	0.08	1.5	1.71	31.8	0.28	5.3	3.23	60.2

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-27
Hematology Laboratory Data by Subject: Differential Counts
(Page 5 of 12)

Subject Number	Subject Classification ^a	Timepoint	BASO Abs (x10 ³ /μL)	BASO % (%)	EOS Abs (x10 ³ /μL)	EOS % (%)	LYMPH Abs (x10 ³ /μL)	LYMPH % (%)	MONO Abs (x10 ³ /μL)	MONO % (%)	NEUT Abs (x10 ³ /μL)	NEUT % (%)
049	M-S	Screening	0.07	0.9	0.32	4.2	2.59	34.1	0.38	5.0	4.24	55.8
		Enrollment	0.05	0.8	0.28	4.5	2.49	40.9	0.38	6.3	2.90	47.5
050	M-S	Screening	0.07	1.3	0.12	2.4	1.72	33.6	0.38	7.4	2.84	55.4
		Enrollment	0.05	0.8	0.33	5.5	2.06	33.9	0.35	5.7	3.30	54.1
051	M-S	Screening	0.10	1.7	0.32	5.4	1.68	28.7	0.42	7.2	3.33	56.9
		Enrollment	0.00	0.0	0.38	9.0 H	1.81	43.0	0.25	6.0	1.76 L	42.0
052	M-S	Screening	0.03	0.6	0.04	0.8	2.17	40.1	0.28	5.1	2.87	53.3
		Enrollment	0.03	0.6	0.04	0.9	2.05	40.8	0.26	5.1	2.64	52.6
053	M-S	Screening	0.14	2.2 H	0.12	1.8	1.82	28.2	0.39	6.1	3.97	61.6
		Enrollment	0.07	0.8	0.09	1.0	2.13	24.0	0.53	6.0	6.06	68.2
054	M-S	Screening	0.04	0.5	0.33	4.7	2.14	30.5	0.37	5.3	4.15	59.0
		Enrollment	0.05	0.6	0.20	2.7	2.20	29.2	0.50	6.6	4.59	60.9
055	M-S	Screening	0.14	1.7	0.05	0.6	1.86	22.8	0.38	4.7	5.72	70.2
		Enrollment	0.07	0.9	0.12	1.6	1.58	20.9	0.66	8.7	5.14	67.9
056	M-S	Screening	0.03	0.4	0.07	0.8	3.33	37.5	0.36	4.1	5.08	57.2
		Enrollment	0.05	0.6	0.09	1.1	2.83	36.6	0.27	3.5	4.48	58.0
057	M-S	Screening	0.06	0.7	0.25	3.1	3.16	39.7	0.58	7.3	3.91	49.2
		Enrollment	0.08	1.0	0.26	3.3	3.95	50.5 H	0.53	6.8	3.01	38.5 L
058	M-S	Screening	0.06	1.0	0.04	0.7	1.59	25.1	0.37	5.9	4.28	67.4
		Enrollment	0.07	1.4	0.11	2.2	1.46	28.5	0.30	5.9	3.17	62.0
059	M-S	Screening	0.14	2.3 H	0.22	3.7	1.67	27.8	0.42	6.9	3.56	59.2
		Enrollment	0.03	0.6	0.10	1.9	2.50	49.5 H	0.48	9.5	1.94 L	38.5 L
060	M-S	Screening	0.03	0.5	0.12	1.9	2.13	32.7	0.59	9.1	3.66	55.9
		Enrollment	0.06	1.0	0.11	1.7	2.02	30.6	0.46	7.0	3.94	59.7

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-27
Hematology Laboratory Data by Subject: Differential Counts
(Page 6 of 12)

Subject Number	Subject Classification ^a	Timepoint	BASO Abs (x10 ⁹ /μL)	BASO % (%)	EOS Abs (x10 ⁹ /μL)	EOS % (%)	LYMPH Abs (x10 ⁹ /μL)	LYMPH % (%)	MONO Abs (x10 ⁹ /μL)	MONO % (%)	NEUT Abs (x10 ⁹ /μL)	NEUT % (%)
061	M-S	Screening	0.09	1.1	0.16	2.1	3.57	44.7	0.50	6.3	3.66	45.8
		Enrollment	0.09	1.2	0.14	1.9	3.58	47.7	0.34	4.5	3.35	44.7
062	M-S	Screening	0.07	0.6	0.13	1.0	2.51	20.1	0.59	4.7	9.21 H	73.6
		Enrollment	0.07	0.7	0.21	2.1	2.37	23.7	0.59	5.9	6.74	67.5
063	M-S	Screening	0.08	1.0	0.12	1.6	1.98	25.2	0.64	8.1	5.03	64.1
		Enrollment	0.08	1.2	0.16	2.6	1.60	25.2	0.47	7.4	4.05	63.7
065	M-S	Screening	0.03	0.7	0.19	4.2	1.67	36.5	0.39	8.5	2.30	50.1
		Enrollment	0.05	0.8	0.26	4.3	2.44	40.2	0.37	6.2	2.95	48.6
066	M-S	Screening	0.04	0.4	0.07	0.7	3.24	30.2	0.32	3.0	7.04	65.7
		Enrollment	0.05	0.5	0.13	1.3	3.17	30.6	0.41	3.9	6.62	63.8
067	M-S	Screening	0.10	1.5	0.29	4.5	1.43	22.5	0.47	7.3	4.11	64.1
		Enrollment	0.10	1.5	0.24	3.8	1.49	23.4	0.44	7.0	4.10	64.3
068	M-S	Screening	0.06	0.6	0.10	1.0	3.00	30.8	0.30	3.1	6.29	64.5
		Enrollment	0.07	0.7	0.15	1.4	2.70	25.8	0.36	3.4	7.18	68.7
069	M-S	Screening	0.06	0.6	0.60 H	5.7	2.48	23.6	0.75	7.1	6.62	63.0
		Enrollment	0.13	1.1	1.00 H	8.6 H	4.12	35.2	0.93 H	7.9	5.53	47.2
071	F-NS	Screening	0.05	0.8	0.14	2.1	2.57	38.5	0.37	5.5	3.54	53.1
		Enrollment	0.02	0.4	0.21	3.9	2.07	39.5	0.37	7.0	2.58	49.2
072	F-NS	Screening	0.03	0.6	0.08	1.5	1.56	31.2	0.22	4.4	3.12	62.3
		Enrollment	0.01	0.5	0.09	2.9	1.11	35.4	0.13	4.1	1.79 L	57.2
073	F-NS	Screening	0.05	0.8	0.19	2.7	1.80	26.2	0.32	4.6	4.54	65.8
		Enrollment	0.03	0.5	0.16	2.6	1.82	30.1	0.29	4.8	3.77	62.1
074	F-NS	Screening	0.02	0.2	0.04	0.4	2.13	21.1	0.26	2.6	7.66 H	75.8 H
		Enrollment	0.03	0.4	0.13	1.6	2.12	25.9	0.38	4.7	5.51	67.4

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-27
Hematology Laboratory Data by Subject: Differential Counts
(Page 7 of 12)

Subject Number	Subject Classification ^a	Timepoint	BASO Abs (x10 ³ /μL)	BASO % (%)	EOS Abs (x10 ³ /μL)	EOS % (%)	LYMPH Abs (x10 ³ /μL)	LYMPH % (%)	MONO Abs (x10 ³ /μL)	MONO % (%)	NEUT Abs (x10 ³ /μL)	NEUT % (%)
075	F-NS	Screening	0.06	1.3	0.05	1.1	2.66	59.5 H	0.18	4.1	1.52 L	34.0 L
		Enrollment	0.04	0.8	0.14	2.7	2.39	48.2	0.15	3.1	2.24	45.1
076	F-NS	Screening	0.04	0.4	0.19	2.0	3.31	34.0	0.34	3.5	5.83	60.0
		Enrollment	0.05	0.5	0.27	2.7	3.38	33.6	0.41	4.1	5.96	59.2
077	F-NS	Screening	0.04	0.5	0.08	0.8	3.03	31.7	0.49	5.1	5.94	62.0
		Enrollment	0.00	0.0	0.00	0.0	3.31	60.0 H	0.06 L	1.0 L	2.15	39.0 L
078	F-NS	Screening	0.04	0.8	0.23	5.0	1.51	32.6	0.25	5.3	2.61	56.3
		Enrollment	0.00	0.0	0.30	9.0 H	2.12	63.0 H	0.10 L	3.0	0.78 LT	23.0 L
079	F-NS	Screening	0.05	0.7	0.14	1.8	2.09	27.4	0.36	4.8	4.98	65.3
		Enrollment	0.06	1.0	0.12	2.0	1.81	29.1	0.40	6.4	3.83	61.5
080	F-NS	Screening	0.07	0.9	0.18	2.5	2.70	37.3	0.40	5.5	3.89	53.7
		Enrollment	0.06	0.9	0.12	1.8	2.30	34.3	0.41	6.1	3.83	56.9
081	F-NS	Screening	0.06	1.3	0.02	0.4	1.47	34.4	0.30	7.0	2.44	56.8
		Enrollment	0.04	0.9	0.03	0.8	1.50	35.8	0.30	7.1	2.33	55.4
082	F-NS	Screening	0.03	0.6	0.08	1.6	1.97	38.7	0.35	6.8	2.67	52.3
		Enrollment	0.03	0.7	0.07	1.8	1.74	42.3	0.27	6.6	2.01	48.6
083	F-NS	Screening	0.05	0.7	0.04	0.5	1.74	25.7	0.23	3.5	4.71	69.6
		Enrollment	0.04	0.5	0.09	1.2	1.93	25.2	0.20	2.6	5.40	70.5
084	F-NS	Screening	0.07	1.5	0.09	2.1	1.63	37.2	0.30	7.0	2.29	52.2
		Enrollment	0.04	1.1	0.08	2.0	1.32	31.9	0.35	8.4	2.35	56.6
085	F-NS	Screening	0.04	0.6	0.14	2.1	1.89	28.8	0.52	8.0	3.97	60.5
		Enrollment	0.07	1.0	0.35	5.0	2.16	31.0	0.35	5.0	4.04	58.0
086	F-NS	Screening	0.03	0.4	0.11	1.5	2.07	27.5	0.42	5.6	4.91	65.1
		Enrollment	0.03	0.5	0.12	2.3	1.75	34.6	0.38	7.4	2.79	55.2

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-27
Hematology Laboratory Data by Subject: Differential Counts
(Page 8 of 12)

Subject Number	Subject Classification ^a	Timepoint	BASO Abs (x10 ⁹ /μL)	BASO % (%)	EOS Abs (x10 ⁹ /μL)	EOS % (%)	LYMPH Abs (x10 ⁹ /μL)	LYMPH % (%)	MONO Abs (x10 ⁹ /μL)	MONO % (%)	NEUT Abs (x10 ⁹ /μL)	NEUT % (%)
087	F-NS	Screening	0.12	1.6	0.16	2.2	2.10	28.4	0.44	5.9	4.58	62.0
		Enrollment	0.10	1.7	0.14	2.6	2.21	39.7	0.35	6.2	2.78	49.8
088	F-NS	Screening	0.02	0.5	0.02	0.5	1.48	30.9	0.24	5.1	3.02	63.0
		Enrollment	0.02	0.6	0.02	0.6	1.34	31.7	0.32	7.6	2.52	59.6
089	F-NS	Screening	0.08	1.2	0.12	1.9	2.94	45.3	0.38	5.9	2.97	45.7
		Enrollment	0.05	1.0	0.15	2.9	2.25	44.9	0.45	9.0	2.12	42.3
090	F-NS	Screening	0.06	0.9	0.17	2.5	2.27	32.0	0.27	3.8	4.31	60.8
		Enrollment	0.05	0.8	0.14	2.3	1.77	28.0	0.24	3.8	4.11	65.0
091	F-NS	Screening	0.05	0.8	0.33	5.3	1.91	30.6	0.35	5.6	3.61	57.7
		Enrollment	0.05	0.8	0.39	6.0	1.87	28.9	0.63	9.8	3.53	54.7
092	F-NS	Screening	0.04	0.9	0.03	0.6	1.67	33.2	0.29	5.7	3.00	59.5
		Enrollment	0.05	0.8	0.07	1.2	1.61	27.3	0.37	6.2	3.82	64.6
093	F-NS	Screening	0.05	1.1	0.17	4.0	1.76	41.7	0.24	5.6	2.02	47.7
		Enrollment	0.05	1.1	0.15	3.3	1.73	37.3	0.22	4.6	2.50	53.7
094	F-NS	Screening	0.00	0.0	0.09	2.0	1.98	46.0	0.34	8.0	1.51 L	35.0 L
		Enrollment	0.03	0.4	0.06	0.8	2.57	34.3	0.35	4.6	4.52	60.0
095	F-NS	Screening	0.03	0.4	0.06	0.9	2.16	32.5	0.31	4.7	4.09	61.5
		Enrollment	0.03	0.5	0.10	1.8	1.60	26.8	0.33	5.6	3.88	65.3
096	F-NS	Screening	0.03	0.4	0.09	1.2	2.85	39.7	0.30	4.2	3.93	54.6
		Enrollment	0.06	0.8	0.08	1.2	2.74	40.3	0.39	5.8	3.52	51.8
097	F-NS	Screening	0.09	1.1	0.06	0.7	2.74	33.1	0.25	3.0	5.16	62.2
		Enrollment	0.05	0.7	0.06	0.7	2.72	33.8	0.26	3.3	4.95	61.6
098	F-NS	Screening	0.03	0.5	0.04	0.8	1.33	26.1	0.24	4.7	3.44	67.9
		Enrollment	0.04	0.7	0.06	0.9	1.84	30.1	0.27	4.4	3.90	64.0

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-27
Hematology Laboratory Data by Subject: Differential Counts
(Page 9 of 12)

Subject Number	Subject Classification ^a	Timepoint	BASO Abs (x10 ³ /μL)	BASO % (%)	EOS Abs (x10 ³ /μL)	EOS % (%)	LYMPH Abs (x10 ³ /μL)	LYMPH % (%)	MONO Abs (x10 ³ /μL)	MONO % (%)	NEUT Abs (x10 ³ /μL)	NEUT % (%)
099	F-NS	Screening	0.04	0.5	0.10	1.3	1.65	22.2	0.29	3.9	5.34	72.0
		Enrollment	0.05	0.9	0.13	2.3	2.09	36.6	0.35	6.1	3.07	53.9
100	F-NS	Screening	0.02	0.4	0.08	1.4	1.75	31.2	0.42	7.6	3.30	59.2
		Enrollment	0.05	0.9	0.09	1.5	1.62	28.2	0.31	5.4	3.66	64.0
101	F-NS	Screening	0.02	0.2	0.18	2.2	2.61	31.4	0.38	4.6	5.12	61.6
		Enrollment	0.04	0.4	0.21	2.2	3.05	31.5	0.50	5.1	5.89	60.8
102	F-NS	Screening	0.06	0.9	0.13	1.8	2.26	32.5	0.30	4.3	4.18	60.3
		Enrollment	0.04	0.6	0.17	2.9	2.07	34.7	0.34	5.8	3.33	55.9
103	F-NS	Screening	0.02	0.3	0.05	0.6	2.43	33.1	0.45	6.2	4.37	59.7
		Enrollment	0.00	0.0	0.27	4.0	2.40	35.0	0.27	4.0	3.92	57.0
104	M-NS	Screening	0.05	1.0	0.10	1.8	2.67	49.5	0.32	6.0	2.25	41.8
		Enrollment	0.07	1.1	0.06	0.9	2.94	46.5	0.43	6.8	2.82	44.6
105	M-NS	Screening	0.04	0.9	0.08	1.7	1.73	33.9	0.36	7.1	2.87	56.4
		Enrollment	0.04	0.8	0.08	1.6	1.96	40.0	0.38	7.7	2.45	49.9
106	M-NS	Screening	0.05	0.7	0.11	1.8	2.76	43.3	0.35	5.5	3.09	48.6
		Enrollment	0.07	1.2	0.10	1.7	2.89	48.1	0.35	5.8	2.60	43.3
107	M-NS	Screening	0.02	0.4	0.06	1.1	2.17	38.1	0.34	6.0	3.11	54.5
		Enrollment	0.03	0.7	0.07	1.4	2.01	39.4	0.42	8.2	2.56	50.3
108	M-NS	Screening	0.09	1.1	0.13	1.6	1.80	22.6	0.41	5.2	5.52	69.5
		Enrollment	0.04	0.5	0.14	1.9	2.49	33.1	0.46	6.2	4.10	58.4
109	M-NS	Screening	0.08	0.8	0.12	1.3	1.87	19.0	0.76	7.8	6.99	71.1
		Enrollment	0.08	1.4	0.10	1.8	1.86	32.0	0.33	5.6	3.44	59.2
110	M-NS	Screening	0.03	0.4	0.17	2.8	1.85	30.3	0.37	6.2	3.66	60.3
		Enrollment	0.05	0.9	0.06	1.0	1.91	30.8	0.37	6.0	3.81	61.4

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-27
Hematology Laboratory Data by Subject: Differential Counts
(Page 10 of 12)

Subject Number	Subject Classification ^a	Timepoint	BASO Abs (x10 ³ /μL)	BASO % (%)	EOS Abs (x10 ³ /μL)	EOS % (%)	LYMPH Abs (x10 ³ /μL)	LYMPH % (%)	MONO Abs (x10 ³ /μL)	MONO % (%)	NEUT Abs (x10 ³ /μL)	NEUT % (%)
111	M-NS	Screening	0.04	0.4	0.05	0.6	1.34	13.7 L	0.26	2.6	8.17 H	82.8 H
		Enrollment	0.04	0.9	0.06	1.2	1.32	26.9	0.43	8.8	3.06	62.3
112	M-NS	Screening	0.03	0.4	0.06	0.8	1.52	20.9	0.37	5.1	5.31	72.8
		Enrollment	0.02	0.5	0.10	2.1	1.34	27.1	0.46	9.3	3.02	61.0
113	M-NS	Screening	0.05	0.8	0.04	0.7	1.52	28.2	0.21	3.9	3.57	66.4
		Enrollment	0.05	1.0	0.04	1.0	1.15	25.5	0.35	7.7	2.91	64.7
114	M-NS	Screening	0.02	0.6	0.08	2.1	1.28	31.6	0.27	6.6	2.39	59.1
		Enrollment	0.04	0.8	0.08	1.6	1.42	30.7	0.29	6.3	2.79	60.6
115	M-NS	Screening	0.07	1.2	0.11	1.9	1.93	33.4	0.39	6.7	3.29	56.8
		Enrollment	0.05	0.8	0.14	2.0	1.73	24.8	0.43	6.1	4.61	66.3
116	M-NS	Screening	0.04	0.6	0.10	1.4	2.20	32.6	0.54	7.9	3.88	57.5
		Enrollment	0.03	0.7	0.07	1.7	1.41	34.8	0.33	8.0	2.24	54.8
117	M-NS	Screening	0.07	0.9	0.03	0.5	1.01	13.9 L	0.38	5.2	5.78	79.5 H
		Enrollment	0.07	1.4	0.05	1.0	1.04	21.3	0.29	6.0	3.45	70.3
118	M-NS	Screening	0.03	0.4	0.14	1.9	1.84	25.2	0.57	7.8	4.74	64.7
		Enrollment	0.04	0.7	0.14	2.3	1.28	21.7	0.42	7.1	4.04	68.1
119	M-NS	Screening	0.06	1.2	0.10	2.1	1.61	33.4	0.32	6.6	2.74	56.7
		Enrollment	0.06	1.1	0.10	2.0	1.96	39.3	0.24	4.9	2.62	52.7
120	M-NS	Screening	0.03	0.7	0.03	0.7	1.27	27.3	0.27	5.9	3.03	65.3
		Enrollment	0.02	0.4	0.06	1.6	1.78	42.6	0.28	6.6	2.03	48.8
121	M-NS	Screening	0.04	0.8	0.11	2.1	1.84	35.7	0.26	5.1	2.90	56.3
		Enrollment	0.04	0.7	0.19	2.9	2.51	38.8	0.40	6.2	3.33	51.4
122	M-NS	Screening	0.05	1.0	0.10	2.0	2.00	40.2	0.47	9.5	2.36	47.4
		Enrollment	0.05	0.8	0.11	1.9	2.34	39.0	0.63	10.5 H	2.86	47.9

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-27
Hematology Laboratory Data by Subject: Differential Counts
(Page 11 of 12)

Subject Number	Subject Classification ^a	Timepoint	BASO Abs (x10 ³ /μL)	BASO % (%)	EOS Abs (x10 ³ /μL)	EOS % (%)	LYMPH Abs (x10 ³ /μL)	LYMPH % (%)	MONO Abs (x10 ³ /μL)	MONO % (%)	NEUT Abs (x10 ³ /μL)	NEUT % (%)
123	M-NS	Screening	0.05	1.0	0.18	3.2	1.46	26.6	0.28	5.1	3.53	64.1
		Enrollment	0.04	0.9	0.11	2.2	1.42	29.6	0.25	5.3	2.96	62.0
124	M-NS	Screening	0.06	1.1	0.20	3.8	1.89	35.4	0.38	7.2	2.80	52.4
		Enrollment	0.06	1.1	0.19	3.6	2.13	39.9	0.31	5.9	2.64	49.5
125	M-NS	Screening	0.06	0.6	0.23	2.3	2.32	22.8	0.43	4.2	7.15	70.2
		Enrollment	0.04	0.6	0.21	2.9	2.19	29.7	0.39	5.3	4.54	61.5
126	M-NS	Screening	0.03	0.3	0.02	0.3	2.13	26.6	0.38	4.8	5.45	68.0
		Enrollment	0.02	0.4	0.04	0.7	2.17	35.4	0.44	7.2	3.44	56.3
127	M-NS	Screening	0.06	1.0	0.06	0.9	1.80	27.0	0.57	8.6	4.16	62.6
		Enrollment	0.06	1.0	0.08	1.3	1.97	33.2	0.44	7.5	3.38	57.0
128	M-NS	Screening	0.04	0.7	0.13	2.3	1.24	22.0	0.44	7.9	3.77	67.1
		Enrollment	0.04	0.7	0.11	2.0	1.54	26.8	0.44	7.6	3.61	63.0
129	M-NS	Screening	0.09	1.0	0.07	0.9	3.11	37.3	0.46	5.5	4.62	55.3
		Enrollment	0.05	0.6	0.10	1.2	3.02	34.2	0.76	8.7	4.87	55.3
130	M-NS	Screening	0.07	0.9	0.11	1.5	2.13	28.3	0.48	6.3	4.75	63.0
		Enrollment	0.12	1.9	0.17	2.6	2.09	31.6	0.57	8.6	3.67	55.4
131	M-NS	Screening	0.00	0.0	0.06	1.0	1.53	27.0	0.45	8.0	3.62	64.0
		Enrollment	0.06	1.4	0.13	3.2	1.37	34.1	0.25	6.3	2.21	55.1
132	M-NS	Screening	0.05	1.1	0.31	6.4	1.69	35.3	0.28	5.8	2.46	51.4
		Enrollment	0.09	1.8	0.41	8.1 H	1.66	32.6	0.30	5.8	2.62	51.7
133	M-NS	Screening	0.04	1.0	0.11	2.8	2.05	50.1 H	0.32	7.8	1.57 L	38.3 L
		Enrollment	0.06	1.2	0.16	3.4	2.12	45.8	0.32	7.0	1.97	42.6
134	M-NS	Screening	0.00	0.0	0.07	2.0	1.25	35.0	0.18	5.0	1.72 L	48.0
		Enrollment	0.04	0.7	0.07	1.3	3.39	58.7 H	0.39	6.8	1.88 L	32.6 L

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-27
Hematology Laboratory Data by Subject: Differential Counts
(Page 12 of 12)

Subject Number	Subject Classification ^a	Timepoint	BASO Abs (x10 ³ /μL)	BASO % (%)	EOS Abs (x10 ³ /μL)	EOS % (%)	LYMPH Abs (x10 ³ /μL)	LYMPH % (%)	MONO Abs (x10 ³ /μL)	MONO % (%)	NEUT Abs (x10 ³ /μL)	NEUT % (%)
135	M-NS	Screening	0.02	0.4	0.10	1.9	2.09	38.7	0.24	4.4	2.93	54.6
		Enrollment	0.01	0.2	0.27	4.7	1.98	35.2	0.40	7.2	2.96	52.7
500	F-NS	Screening	0.04	0.7	0.05	0.9	1.87	33.2	0.17	3.1	3.51	62.1
		Enrollment	0.04	0.7	0.11	2.0	2.01	35.7	0.21	3.7	3.26	57.9
501	F-NS	Screening	0.08	1.0	0.20	2.5	2.66	33.1	0.29	3.6	4.79	59.7
		Enrollment	0.05	0.9	0.09	1.5	1.87	30.4	0.32	5.2	3.82	62.1
502	F-S	Screening	0.05	0.4	0.11	1.0	3.39	29.4	0.46	4.0	7.49 H	65.1
		Enrollment	0.05	0.5	0.12	1.4	2.67	29.8	0.35	3.9	5.78	64.4
503	F-S	Screening	0.05	0.5	0.21	2.4	2.49	28.6	0.34	3.9	5.62	64.5
		Enrollment	0.05	0.4	0.22	1.8	1.92	15.9	0.46	3.8	9.43 H	78.1 H
504	F-S	Screening	0.06	0.6	0.23	2.4	3.65	38.7	0.46	4.8	5.06	53.5
		Enrollment	0.11	1.1	0.28	2.7	3.34	32.0	0.53	5.0	6.16	59.1
505	F-NS	Screening	0.08	1.2	0.23	3.2	2.84	39.5	0.45	6.2	3.59	50.0
		Enrollment	0.07	1.0	0.27	3.8	2.25	31.9	0.43	6.0	4.05	57.3
506	F-S	Screening	0.04	0.6	0.09	1.2	2.24	31.1	0.39	5.3	4.47	61.8
		Enrollment	0.05	0.6	0.10	1.2	2.03	24.9	0.38	4.7	5.60	68.6

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-28
 Urinalysis Laboratory Data by Subject: General
 (Page 1 of 12)

Subject Number	Subject Classification ^a	Timepoint	Color	pH	Specific Gravity	Urobilinogen
001	F-S	Screening	Norm	6	1.022	Norm
		Enrollment	Norm	5	1.019	Norm
002	F-S	Screening	Norm	5	1.028	Norm
		Enrollment	Norm	6	1.027	Norm
003	F-S	Screening	Norm	7	1.020	Norm
		Enrollment	Norm	5	1.028	Norm
004	F-S	Screening	Norm	5	1.027	Norm
		Enrollment	Norm	5	1.029	Norm
005	F-S	Screening	Norm	6	1.033	Norm
		Enrollment	Norm	6	1.028	Norm
006	F-S	Screening	Norm	5	1.007 L	Norm
		Enrollment	Norm	6	1.010	Norm
007	F-S	Screening	Norm	6	1.008 L	Norm
		Enrollment	Norm	6	1.020	Norm
008	F-S	Screening	Norm	6	1.008 L	Norm
		Enrollment	Norm	7	1.009 L	Norm
009	F-S	Screening	Norm	5	1.005 L	Norm
		Enrollment	Norm	7	1.008	Norm
010	F-S	Screening	Norm	5	1.026	Norm
		Enrollment	Norm	7	1.007 L	Norm
011	F-S	Screening	Norm	5	1.028	Norm
		Enrollment	Norm	6	1.023	Norm
012	F-S	Screening	Norm	5	1.008 L	Norm
		Enrollment	Norm	5	1.008 L	Norm

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630183

Listing 16.5-28
Urinalysis Laboratory Data by Subject: General
(Page 2 of 12)

Subject Number	Subject Classification ^a	Timepoint	Color	pH	Specific Gravity	Urobilinogen
013	F-S	Screening	Norm	6	1.008 L	Norm
		Enrollment	Norm	6	1.009 L	Norm
014	F-S	Screening	Norm	5	1.017	Norm
		Enrollment	Norm	6	1.019	Norm
015	F-S	Screening	Norm	5	1.009 L	Norm
		Enrollment	Norm	5	1.007 L	Norm
016	F-S	Screening	Norm	5	1.006 L	Norm
		Enrollment	Norm	6	1.007 L	Norm
017	F-S	Screening	Norm	6	1.014	Norm
		Enrollment	Norm	5	1.005 L	Norm
018	F-S	Screening	Norm	5	1.009 L	Norm
		Enrollment	Norm	6	1.015	Norm
019	F-S	Screening	Norm	6	1.016	Norm
		Enrollment	Norm	5	1.019	Norm
020	F-S	Screening	Norm	5	1.004 L	Norm
		Enrollment	Norm	5	1.005 L	Norm
021	F-S	Screening	Norm	5	1.010	Norm
		Enrollment	Norm	6	1.027	Norm
022	F-S	Screening	Norm	5	1.011	Norm
		Enrollment	Norm	7	1.018	Norm
023	F-S	Screening	Norm	6	1.025	Norm
		Enrollment	Norm	5	1.022	Norm
024	F-S	Screening	Norm	5	1.008 L	Norm
		Enrollment	Norm	5	1.015	Norm

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-28
Urinalysis Laboratory Data by Subject: General
(Page 3 of 12)

Subject Number	Subject Classification ^a	Timepoint	Color	pH	Specific Gravity	Urobilinogen
025	F-S	Screening	Norm	5	1.023	Norm
		Enrollment	Norm	5	1.017	Norm
026	F-S	Screening	Norm	6	1.028	Norm
		Enrollment	Norm	5	1.025	Norm
027	F-S	Screening	Norm	5	1.006 L	Norm
		Enrollment	Norm	7	1.011	Norm
028	F-S	Screening	Norm	5	1.011	Norm
		Enrollment	Norm	5	1.005 L	Norm
029	F-S	Screening	Norm	6	1.020	Norm
		Enrollment	Norm	6	1.023	Norm
030	F-S	Screening	Norm	5	1.009 L	Norm
		Enrollment	Norm	5	1.010	Norm
031	F-S	Screening	Norm	6	1.009 L	Norm
		Enrollment	Norm	6	1.015	Norm
032	F-S	Screening	Norm	6	1.010	Norm
		Enrollment	Norm	7	1.011	Norm
033	F-S	Screening	Norm	7	1.029	Norm
		Enrollment	Norm	6	1.004 L	Norm
034	F-S	Screening	Norm	6	1.012	Norm
		Enrollment	Norm	7	1.019	Norm
035	F-S	Screening	Norm	5	1.011	Norm
		Enrollment	Norm	6	1.007 L	Norm
036	M-S	Screening	Norm	5	1.026	Norm
		Enrollment	Norm	6	1.009 L	Norm

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630185

Listing 16.5-28
Urinalysis Laboratory Data by Subject: General
(Page 4 of 12)

Subject Number	Subject Classification ^a	Timepoint	Color	pH	Specific Gravity	Urobilinogen
037	M-S	Screening	Norm	6	1.007 L	Norm
		Enrollment	Norm	5	1.021	Norm
038	M-S	Screening	Norm	5	1.025	Norm
		Enrollment	Norm	5	1.021	Norm
039	M-S	Screening	Norm	7	1.022	Norm
		Enrollment	Norm	5	1.022	Norm
040	M-S	Screening	Norm	7	1.019	Norm
		Enrollment	Norm	6	1.029	Norm
041	M-S	Screening	Norm	5	1.029	Norm
		Enrollment	Norm	5	1.027	Norm
042	M-S	Screening	Norm	6	1.012	Norm
		Enrollment	Norm	6	1.009 L	Norm
043	M-S	Screening	Norm	6	1.022	Norm
		Enrollment	Norm	5	1.022	Norm
044	M-S	Screening	Norm	5	1.029	Norm
		Enrollment	Norm	6	1.029	Norm
045	M-S	Screening	Norm	5	1.027	Norm
		Enrollment	Norm	6	1.025	Norm
046	M-S	Screening	Norm	5	1.023	Norm
		Enrollment	Norm	6	1.027	Norm
047	M-S	Screening	Norm	5	1.023	Norm
		Enrollment	Norm	5	1.025	Norm
048	M-S	Screening	Norm	6	1.026	Norm
		Enrollment	Norm	7	1.027	Norm

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-28
Urinalysis Laboratory Data by Subject: General
(Page 5 of 12)

Subject Number	Subject Classification ^a	Timepoint	Color	pH	Specific Gravity	Urobilinogen
049	M-S	Screening	Norm	5	1.015	Norm
		Enrollment	Norm	6	1.023	Norm
050	M-S	Screening	Norm	6	1.019	Norm
		Enrollment	Norm	6	1.010	Norm
051	M-S	Screening	Norm	5	1.016	Norm
		Enrollment	Norm	5	1.029	Norm
052	M-S	Screening	Norm	6	1.025	Norm
		Enrollment	Norm	7	1.029	Norm
053	M-S	Screening	Norm	5	1.007 L	Norm
		Enrollment	Norm	6	1.023	Norm
054	M-S	Screening	Norm	6	1.020	Norm
		Enrollment	Norm	5	1.026	Norm
055	M-S	Screening	Norm	6	1.025	Norm
		Enrollment	Norm	5	1.025	Norm
056	M-S	Screening	Norm	5	1.008 L	Norm
		Enrollment	Norm	5	1.027	Norm
057	M-S	Screening	Norm	5	1.026	Norm
		Enrollment	Norm	6	1.028	Norm
058	M-S	Screening	Norm	5	1.004 L	Norm
		Enrollment	Norm	6	1.007 L	Norm
059	M-S	Screening	Norm	5	1.007 L	Norm
		Enrollment	Norm	7	1.011	Norm
060	M-S	Screening	Norm	5	1.025	Norm
		Enrollment	Norm	5	1.022	Norm

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-28
Urinalysis Laboratory Data by Subject: General
(Page 6 of 12)

Subject Number	Subject Classification ^a	Timepoint	Color	pH	Specific Gravity	Urobilinogen
061	M-S	Screening	Norm	6	1.029	Norm
		Enrollment	Norm	6	1.028	Norm
062	M-S	Screening	Norm	5	1.020	Norm
		Enrollment	Norm	6	1.012	Norm
063	M-S	Screening	Norm	5	1.009 L	Norm
		Enrollment	Norm	6	1.028	Norm
065	M-S	Screening	Norm	6	1.013	Norm
		Enrollment	Norm	7	1.022	Norm
066	M-S	Screening	Norm	5	1.008 L	Norm
		Enrollment	Norm	6	1.012	Norm
067	M-S	Screening	Norm	5	1.007 L	Norm
		Enrollment	Norm	5	1.010	Norm
068	M-S	Screening	Norm	5	1.018	Norm
		Enrollment	Norm	6	1.008 L	Norm
069	M-S	Screening	Norm	5	1.019	Norm
		Enrollment	Norm	6	1.027	Norm
071	F-NS	Screening	Norm	5	1.009 L	Norm
		Enrollment	Norm	6	1.018	Norm
072	F-NS	Screening	Norm	5	1.004 L	Norm
		Enrollment	Norm	5	1.009 L	Norm
073	F-NS	Screening	Norm	6	1.026	Norm
		Enrollment	Norm	6	1.023	Norm
074	F-NS	Screening	Norm	5	1.008 L	Norm
		Enrollment	Norm	6	1.011	Norm

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630188

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-28
Urinalysis Laboratory Data by Subject: General
(Page 7 of 12)

Subject Number	Subject Classification ^a	Timepoint	Color	pH	Specific Gravity	Urobilinogen
075	F-NS	Screening	Norm	6	1.023	Norm
		Enrollment	Norm	6	1.025	Norm
076	F-NS	Screening	Norm	6	1.028	Norm
		Enrollment	Norm	5	1.030	Norm
077	F-NS	Screening	Norm	5	1.008 L	Norm
		Enrollment	Norm	7	1.007 L	Norm
078	F-NS	Screening	Norm	6	1.029	Norm
		Enrollment	Norm	6	1.019	Norm
079	F-NS	Screening	Norm	7	1.027	Norm
		Enrollment	Norm	8	1.021	Norm
080	F-NS	Screening	Norm	6	1.008 L	Norm
		Enrollment	Norm	5	1.006 L	Norm
081	F-NS	Screening	Norm	7	1.016	Norm
		Enrollment	Norm	5	1.006 L	Norm
082	F-NS	Screening	Norm	5	1.029	Norm
		Enrollment	Norm	6	1.016	Norm
083	F-NS	Screening	Norm	6	1.013	Norm
		Enrollment	Norm	7	1.011	Norm
084	F-NS	Screening	Norm	6	1.007	Norm
		Enrollment	Norm	6	1.010	Norm
085	F-NS	Screening	Norm	6	1.021	Norm
		Enrollment	Norm	7	1.026	Norm
086	F-NS	Screening	Norm	5	1.026	Norm
		Screening	Norm	6	1.027	Norm
		Enrollment	Norm	5	1.028	Norm

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630189

Draft 1: 24 July 2002

Page 14842 of 15132

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-28
 Urinalysis Laboratory Data by Subject: General
 (Page 8 of 12)

Subject Number	Subject Classification ^a	Timepoint	Color	pH	Specific Gravity	Urobilinogen
087	F-NS	Screening	Norm	6	1.012	Norm
		Enrollment	Norm	5	1.007 L	Norm
088	F-NS	Screening	Norm	5	1.019	Norm
		Enrollment	Norm	5	1.015	Norm
089	F-NS	Screening	Norm	5	1.010	Norm
		Enrollment	Norm	5	1.022	Norm
090	F-NS	Screening	Norm	6	1.013	Norm
		Enrollment	Norm	6	1.012	Norm
091	F-NS	Screening	Norm	5	1.025	Norm
		Enrollment	Norm	5	1.021	Norm
092	F-NS	Screening	Norm	7	1.012	Norm
		Enrollment	Norm	7	1.007 L	Norm
093	F-NS	Screening	Norm	5	1.007 L	Norm
		Enrollment	Norm	6	1.008 L	Norm
094	F-NS	Screening	Norm	5	1.029	Norm
		Enrollment	Norm	6	1.004 L	Norm
095	F-NS	Screening	Norm	6	1.013	Norm
		Enrollment	Norm	7	1.014	Norm
096	F-NS	Screening	Norm	7	1.014	Norm
		Enrollment	Norm	6	1.013	Norm
097	F-NS	Screening	Norm	5	1.021	Norm
		Enrollment	Norm	6	1.009 L	Norm
098	F-NS	Screening	Norm	5	1.011	Norm
		Enrollment	Norm	5	1.012	Norm

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630190

Listing 16.5-28
Urinalysis Laboratory Data by Subject: General
(Page 9 of 12)

Subject Number	Subject Classification ^a	Timepoint	Color	pH	Specific Gravity	Urobilinogen
099	F-NS	Screening	Norm	5	1.014	Norm
		Enrollment	Norm	5	1.025	Norm
100	F-NS	Screening	Norm	6	1.023	Norm
		Enrollment	Norm	5	1.023	Norm
101	F-NS	Screening	Norm	7	1.015	Norm
		Enrollment	Norm	5	1.010	Norm
102	F-NS	Screening	Norm	7	1.025	Norm
		Enrollment	Norm	6	1.020	Norm
103	F-NS	Screening	Norm	5	1.019	Norm
		Enrollment	Norm	5	1.017	Norm
104	M-NS	Screening	Norm	6	1.029	Norm
		Enrollment	Norm	5	1.016	Norm
105	M-NS	Screening	Norm	5	1.005 L	Norm
		Enrollment	Norm	5	1.017	Norm
106	M-NS	Screening	Norm	5	1.012	Norm
		Enrollment	Norm	5	1.006 L	Norm
107	M-NS	Screening	Norm	6	1.019	Norm
		Enrollment	Norm	6	1.029	Norm
108	M-NS	Screening	Norm	6	1.023	Norm
		Enrollment	Norm	5	1.021	Norm
109	M-NS	Screening	Norm	6	1.026	Norm
		Enrollment	Norm	5	1.031	Norm
110	M-NS	Screening	Norm	5	1.025	Norm
		Enrollment	Norm	5	1.028	Norm

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-28
Urinalysis Laboratory Data by Subject: General
(Page 10 of 12)

Subject Number	Subject Classification*	Timepoint	Color	pH	Specific Gravity	Urobilinogen
111	M-NS	Screening	Norm	5	1.031	Norm
		Enrollment	Norm	7	1.026	Norm
112	M-NS	Screening	Norm	5	1.009 L	Norm
		Enrollment	Norm	5	1.011	Norm
113	M-NS	Screening	Norm	6	1.015	Norm
		Enrollment	Norm	5	1.022	Norm
114	M-NS	Screening	Norm	5	1.005 L	Norm
		Enrollment	Norm	5	1.008 L	Norm
115	M-NS	Screening	Norm	7	1.025	Norm
		Enrollment	Norm	5	1.030	Norm
116	M-NS	Screening	Norm	5	1.023	Norm
		Enrollment	Norm	7	1.014	Norm
117	M-NS	Screening	Norm	5	1.020	Norm
		Enrollment	Norm	5	1.030	Norm
118	M-NS	Screening	Norm	5	1.008 L	Norm
		Enrollment	Norm	6	1.006 L	Norm
119	M-NS	Screening	Norm	5	1.027	Norm
		Enrollment	Norm	5	1.026	Norm
120	M-NS	Screening	Norm	5	1.028	Norm
		Enrollment	Norm	6	1.035 H	Norm
121	M-NS	Screening	Norm	6	1.011	Norm
		Enrollment	Norm	6	1.014	Norm
122	M-NS	Screening	Norm	7	1.028	Norm
		Enrollment	Norm	6	1.032	Norm

* Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-28
Urinalysis Laboratory Data by Subject: General
(Page 11 of 12)

Subject Number	Subject Classification ^a	Timepoint	Color	pH	Specific Gravity	Urobilinogen
123	M-NS	Screening	Norm	5	1.012	Norm
		Enrollment	Norm	5	1.021	Norm
124	M-NS	Screening	Norm	5	1.031	Norm
		Enrollment	Norm	5	1.021	Norm
125	M-NS	Screening	Norm	6	1.020	Norm
		Enrollment	Norm	5	1.016	Norm
126	M-NS	Screening	Norm	7	1.020	Norm
		Enrollment	Norm	6	1.028	Norm
127	M-NS	Screening	Norm	7	1.017	Norm
		Enrollment	Norm	5	1.028	Norm
128	M-NS	Screening	Norm	5	1.019	Norm
		Enrollment	Norm	5	1.019	Norm
129	M-NS	Screening	Norm	6	1.018	Norm
		Enrollment	Norm	5	1.006 L	Norm
130	M-NS	Screening	Norm	6	1.004 L	Norm
		Enrollment	Norm	6	1.004 L	Norm
131	M-NS	Screening	Norm	6	1.011	Norm
		Enrollment	Norm	6	1.009 L	Norm
132	M-NS	Screening	Norm	5	1.015	Norm
		Enrollment	Norm	6	1.019	Norm
133	M-NS	Screening	Norm	6	1.007 L	Norm
		Enrollment	Norm	6	1.022	Norm
134	M-NS	Screening	Norm	5	1.005 L	Norm
		Enrollment	Norm	5	1.006 L	Norm

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-28
Urinalysis Laboratory Data by Subject: General
(Page 12 of 12)

Subject Number	Subject Classification ^a	Timepoint	Color	pH	Specific Gravity	Urobilinogen
135	M-NS	Screening	Norm	5	1.020	Norm
		Enrollment	Norm	7	1.019	Norm
500	F-NS	Screening	Norm	6	1.014	Norm
		Enrollment	Norm	5	1.006 L	Norm
501	F-NS	Screening	Norm	7	1.007 L	Norm
		Enrollment	Norm	6	1.006 L	Norm
502	F-S	Screening	Norm	5	1.010	Norm
		Enrollment	Norm	7	1.026	Norm
503	F-S	Screening	Norm	5	1.028	Norm
		Enrollment	Norm	6	1.022	Norm
504	F-S	Screening	Norm	5	1.005 L	Norm
		Enrollment	Norm	5	1.012	Norm
505	F-NS	Screening	Norm	6	1.010	Norm
		Enrollment	Norm	5	1.012	Norm
506	F-S	Screening	Norm	5	1.015	Norm
		Enrollment	Norm	5	1.021	Norm

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-29
Urinalysis Laboratory Data by Subject: Dipstick
(Page 1 of 12)

Subject Number	Subject Classification ^a	Timepoint	Glucose	Protein	Ketones	Nitrite	Leukocytes	Bilirubin	Occult Blood
001	F-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
002	F-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	+++ II Neg
003	F-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
004	F-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
005	F-S	Screening Enrollment	Neg Neg	Trace Trace	++ II Neg	Neg Neg	Neg Neg	Neg Neg	Neg +++ II
006	F-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
007	F-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
008	F-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Trace
009	F-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
010	F-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Trace Neg
011	F-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
012	F-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-29
Urinalysis Laboratory Data by Subject: Dipstick
(Page 2 of 12)

Subject Number	Subject Classification ^a	Timepoint	Glucose	Protein	Ketones	Nitrite	Leukocytes	Bilirubin	Occult Blood
013	F-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg + II	Neg Neg	Neg Neg
014	F-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
015	F-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	++ II Neg
016	F-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	+ II Neg	Neg Neg	Neg Neg
017	F-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
018	F-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
019	F-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	+ II Neg
020	F-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	+ I+ H Neg
021	F-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Trace + H
022	F-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
023	F-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Trace Neg
024	F-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-29
Urinalysis Laboratory Data by Subject: Dipstick
(Page 3 of 12)

Subject Number	Subject Classification ^a	Timepoint	Glucose	Protein	Ketones	Nitrite	Leukocytes	Bilirubin	Occult Blood
025	F-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
026	F-S	Screening Enrollment	Neg Neg	Neg Neg	Trace Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
027	F-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
028	F-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
029	F-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Trace	Neg Neg	Neg Trace
030	F-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
031	F-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
032	F-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
033	F-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
034	F-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
035	F-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
036	M-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-29
Urinalysis Laboratory Data by Subject: Dipstick
(Page 4 of 12)

Subject Number	Subject Classification ^a	Timepoint	Glucose	Protein	Ketones	Nitrite	Leukocytes	Bilirubin	Occult Blood
037	M-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
038	M-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
039	M-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
040	M-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Trace
041	M-S	Screening Enrollment	Neg Neg	Neg Trace	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
042	M-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
043	M-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
044	M-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
045	M-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
046	M-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Trace	Neg Neg	Neg Neg	Neg Neg	Neg Neg
047	M-S	Screening Enrollment	Neg Neg	Neg Trace	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
048	M-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-29
Urinalysis Laboratory Data by Subject: Dipstick
(Page 5 of 12)

Subject Number	Subject Classification ^a	Timepoint	Glucose	Protein	Ketones	Nitrite	Leukocytes	Bilirubin	Occult Blood
049	M-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
050	M-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
051	M-S	Screening Enrollment	Neg Neg	Neg + H	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
052	M-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
053	M-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
054	M-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
055	M-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
056	M-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
057	M-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
058	M-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
059	M-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
060	M-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-29
Urinalysis Laboratory Data by Subject: Dipstick
(Page 6 of 12)

Subject Number	Subject Classification ^a	Timepoint	Glucose	Protein	Ketones	Nitrite	Leukocytes	Bilirubin	Occult Blood
061	M-S	Screening Enrollment	Neg Neg	Trace Neg	Trace Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
062	M-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
063	M-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
065	M-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
066	M-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
067	M-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
068	M-S	Screening Enrollment	Neg Neg	Neg Neg	+ II + II	Neg Neg	Neg Neg	Neg Neg	Neg Neg
069	M-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
071	F-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg +++ H
072	F-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg +++ H
073	F-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
074	F-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-29
Urinalysis Laboratory Data by Subject: Dipstick
(Page 7 of 12)

Subject Number	Subject Classification ^a	Timepoint	Glucose	Protein	Ketones	Nitrite	Leukocytes	Bilirubin	Occult Blood
075	F-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg + H
076	F-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
077	F-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
078	F-NS	Screening Enrollment	Neg Neg	Trace Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	+++ H Neg
079	F-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Pos H Pos H	Neg Neg	Neg Neg	Neg + H
080	F-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Trace	Neg Neg	Neg Neg
081	F-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
082	F-NS	Screening Enrollment	Neg Neg	Neg Neg	Trace Neg	Neg Neg	Neg Neg	Neg Neg	Trace Neg
083	F-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
084	F-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
085	F-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Trace	Neg Neg	Neg Neg	Neg Neg	Neg Neg
086	F-NS	Screening Screening Enrollment	Neg Neg Neg	Neg Neg Neg	Neg Neg Neg	Neg Neg Neg	Neg Neg Neg	Neg Neg Neg	+ H + H +++ H

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-29
Urinalysis Laboratory Data by Subject: Dipstick
(Page 8 of 12)

Subject Number	Subject Classification ^a	Timepoint	Glucose	Protein	Ketones	Nitrite	Leukocytes	Bilirubin	Occult Blood
087	F-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
088	F-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	+ H + H
089	F-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Trace
090	F-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
091	F-NS	Screening Enrollment	Neg Trace	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg ++ H
092	F-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
093	F-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Trace	Neg Neg	Neg Neg
094	F-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
095	F-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	++ H +++ H	Neg Neg	Neg Neg
096	F-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
097	F-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Trace	Neg Neg	Neg Neg
098	F-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-29
Urinalysis Laboratory Data by Subject: Dipstick
(Page 9 of 12)

Subject Number	Subject Classification ^a	Timepoint	Glucose	Protein	Ketones	Nitrite	Leukocytes	Bilirubin	Occult Blood
099	F-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg + H
100	F-NS	Screening Enrollment	Neg Neg	Neg Neg	+ H Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
101	F-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	+ H Neg	Neg Neg	++ H Neg
102	F-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
103	F-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Trace
104	M-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
105	M-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
106	M-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
107	M-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
108	M-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
109	M-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
110	M-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-29
Urinalysis Laboratory Data by Subject: Dipstick
(Page 10 of 12)

Subject Number	Subject Classification ^a	Timepoint	Glucose	Protein	Ketones	Nitrite	Leukocytes	Bilirubin	Occult Blood
111	M-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
112	M-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
113	M-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
114	M-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
115	M-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
116	M-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
117	M-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
118	M-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
119	M-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
120	M-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Trace	Neg Neg	Neg Neg	Neg Neg	Neg Neg
121	M-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
122	M-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Trace	Neg Neg	Neg Neg	Neg Neg	Neg Neg

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-29
Urinalysis Laboratory Data by Subject: Dipstick
(Page 11 of 12)

Subject Number	Subject Classification ^a	Timepoint	Glucose	Protein	Ketones	Nitrite	Leukocytes	Bilirubin	Occult Blood
123	M-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
124	M-NS	Screening Enrollment	Neg Neg	Trace Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
125	M-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
126	M-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
127	M-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
128	M-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
129	M-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
130	M-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
131	M-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
132	M-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
133	M-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
134	M-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-29
Urinalysis Laboratory Data by Subject: Dipstick
(Page 12 of 12)

Subject Number	Subject Classification ^a	Timepoint	Glucose	Protein	Ketones	Nitrite	Leukocytes	Bilirubin	Occult Blood
135	M-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
500	F-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
501	F-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
502	F-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
503	F-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
504	F-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
505	F-NS	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg
506	F-S	Screening Enrollment	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg	Neg Neg

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-30
Urinalysis Laboratory Data by Subject: Microscopies
(Page 1 of 12)

Subject Number	Subject Classification ^a	Timepoint	Result
001	F-S	Screening Enrollment	Bacteria Bacteria
002	F-S	Screening Enrollment	RBC 0-1 WBC 3-5 WBC 6-12
003	F-S	Screening Enrollment	Neg Neg
004	F-S	Screening Enrollment	Neg Neg
005	F-S	Screening Enrollment	Neg RBC:TNIC
006	F-S	Screening Enrollment	Neg Neg
007	F-S	Screening Enrollment	Neg Neg
008	F-S	Screening Enrollment	RBC 2-4 RBC 4-8 WBC 1-3
009	F-S	Screening Enrollment	Neg Neg
010	F-S	Screening Enrollment	Neg Bacteria
011	F-S	Screening Enrollment	Neg RBC 0-1 WBC 7-15
012	F-S	Screening Enrollment	Neg Neg

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-30
Urinalysis Laboratory Data by Subject: Microscopies
(Page 2 of 12)

Subject Number	Subject Classification ^a	Timepoint	Result
013	F-S	Screening Enrollment	Bacteria WBC 1-3 Bacteria
014	F-S	Screening Enrollment	Bacteria Neg
015	F-S	Screening Enrollment	RBC 3-5 WBC 14-22 WBC 1-3
016	F-S	Screening Enrollment	WBC 6-10 Bacteria Neg
017	F-S	Screening Enrollment	RBC 0-1 WBC 3-5 Neg
018	F-S	Screening Enrollment	Bacteria Neg
019	F-S	Screening Enrollment	WBC 0-1 WBC 9-17 Bacteria
020	F-S	Screening Enrollment	RBC 48-66 Neg
021	F-S	Screening Enrollment	RBC 0-1 RBC 8-18 WBC 9-17 Bacteria
022	F-S	Screening Enrollment	Neg Neg
023	F-S	Screening Enrollment	RBC 0-1 WBC 0-1 Bacteria Neg

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-30
Urinalysis Laboratory Data by Subject: Microscopics
(Page 3 of 12)

Subject Number	Subject Classification ^a	Timepoint	Result
024	F-S	Screening Enrollment	Neg WBC 0-1 Bacteria
025	F-S	Screening Enrollment	RBC 2-4 Neg
026	F-S	Screening Enrollment	Neg Neg
027	F-S	Screening Enrollment	Neg Neg
028	F-S	Screening Enrollment	Neg Neg
029	F-S	Screening Enrollment	WBC 7-13 Bacteria Neg
030	F-S	Screening Enrollment	Neg Neg
031	F-S	Screening Enrollment	Neg Neg
032	F-S	Screening Enrollment	Neg Neg
033	F-S	Screening Enrollment	WBC 1-3 Neg
034	F-S	Screening Enrollment	Neg Bacteria
035	F-S	Screening Enrollment	Neg Neg

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-30
Urinalysis Laboratory Data by Subject: Microscopies
(Page 4 of 12)

Subject Number	Subject Classification ^a	Timepoint	Result
036	M-S	Screening Enrollment	Neg Neg
037	M-S	Screening Enrollment	Neg Neg
038	M-S	Screening Enrollment	Neg WBC 0-1
039	M-S	Screening Enrollment	Neg WBC 2-4
040	M-S	Screening Enrollment	Neg RBC 0-1 WBC 1-3 Bacteria
041	M-S	Screening Enrollment	Neg Neg
042	M-S	Screening Enrollment	Neg Neg
043	M-S	Screening Enrollment	Neg Neg
044	M-S	Screening Enrollment	Neg Neg
045	M-S	Screening Enrollment	Neg Neg
046	M-S	Screening Enrollment	Neg Neg
047	M-S	Screening Enrollment	Neg Neg

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-30
Urinalysis Laboratory Data by Subject: Microscopics
(Page 5 of 12)

Subject Number	Subject Classification ^a	Timepoint	Result
048	M-S	Screening Enrollment	Neg Neg
049	M-S	Screening Enrollment	WBC 2-4 Neg
050	M-S	Screening Enrollment	WBC 1-3 Neg
051	M-S	Screening Enrollment	Neg WBC 0-1
052	M-S	Screening Enrollment	WBC 0-1 Neg
053	M-S	Screening Enrollment	Neg Neg
054	M-S	Screening Enrollment	Neg Neg
055	M-S	Screening Enrollment	Neg Neg
056	M-S	Screening Enrollment	Neg Neg
057	M-S	Screening Enrollment	Neg Neg
058	M-S	Screening Enrollment	Neg Neg
059	M-S	Screening Enrollment	Neg Neg
060	M-S	Screening Enrollment	WBC 1-3 Neg

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-30
Urinalysis Laboratory Data by Subject: Microscopics
(Page 6 of 12)

Subject Number	Subject Classification ^a	Timepoint	Result
061	M-S	Screening Enrollment	Neg Neg
062	M-S	Screening Enrollment	Neg Neg
063	M-S	Screening Enrollment	Neg Neg
065	M-S	Screening Enrollment	Neg Neg
066	M-S	Screening Enrollment	Neg Neg
067	M-S	Screening Enrollment	WBC 0-1 Neg
068	M-S	Screening Enrollment	WBC 0-1 Neg
069	M-S	Screening Enrollment	WBC 2-4 Neg
071	F-NS	Screening Enrollment	Neg RBC 1-3 WBC 4-8
072	F-NS	Screening Enrollment	Neg RBC 10-20
073	F-NS	Screening Enrollment	RBC 1-3 Bacteria
074	F-NS	Screening Enrollment	Neg Neg
075	F-NS	Screening Enrollment	Neg RBC 5-11 WBC 0-1

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-30
Urinalysis Laboratory Data by Subject: Microscopics
(Page 7 of 12)

Subject Number	Subject Classification ^a	Timepoint	Result
076	F-NS	Screening Enrollment	Neg Neg
077	F-NS	Screening Enrollment	Neg Neg
078	F-NS	Screening Enrollment	RBC:TNTC Neg
079	F-NS	Screening Enrollment	Neg RBC 3-7
080	F-NS	Screening Enrollment	Bacteria WBC 1-3 Bacteria
081	F-NS	Screening Enrollment	Neg Neg
082	F-NS	Screening Enrollment	RBC 1-3 WBC 0-1 RBC 1-3
083	F-NS	Screening Enrollment	Neg Neg
084	F-NS	Screening Enrollment	Neg Neg
085	F-NS	Screening Enrollment	Neg Neg
086	F-NS	Screening Screening Enrollment	WBC 4-8 Bacteria WBC 2-4 WBC 4-8 Bacteria

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-30
 Urinalysis Laboratory Data by Subject: Microscopics
 (Page 8 of 12)

Subject Number	Subject Classification ^a	Timepoint	Result
087	F-NS	Screening Enrollment	Neg Neg
088	F-NS	Screening Enrollment	RBC 0-1 Bacteria Neg
089	F-NS	Screening Enrollment	Neg RBC 3-5 WBC 0-1
090	F-NS	Screening Enrollment	Neg Bacteria
091	F-NS	Screening Enrollment	Bacteria Neg
092	F-NS	Screening Enrollment	Neg Bacteria
093	F-NS	Screening Enrollment	Neg Neg
094	F-NS	Screening Enrollment	WBC 1-3 Neg
095	F-NS	Screening Enrollment	WBC 8-16 Bacteria RBC 0-1
096	F-NS	Screening Enrollment	Neg Neg
097	F-NS	Screening Enrollment	Neg Neg
098	F-NS	Screening Enrollment	Neg Neg

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630214

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-30
Urinalysis Laboratory Data by Subject: Microscopies
(Page 9 of 12)

Subject Number	Subject Classification*	Timepoint	Result
099	F-NS	Screening	WBC 3-7
		Enrollment	Bacteria RBC 1-3 WBC 0-1
100	F-NS	Screening	Neg
		Enrollment	Neg
101	F-NS	Screening	RBC 3-7
		Enrollment	WBC 6-12 Neg
102	F-NS	Screening	Neg
		Enrollment	WBC 1-3
103	F-NS	Screening	Neg
		Enrollment	Bacteria
104	M-NS	Screening	Neg
		Enrollment	Neg
105	M-NS	Screening	Neg
		Enrollment	Neg
106	M-NS	Screening	Neg
		Enrollment	Neg
107	M-NS	Screening	Neg
		Enrollment	Neg
108	M-NS	Screening	Neg
		Enrollment	Neg
109	M-NS	Screening	Neg
		Enrollment	Neg
110	M-NS	Screening	Neg
		Enrollment	Neg

* Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630215

Draft 1: 24 July 2002

Page 14868 of 15132

Listing 16.5-30
Urinalysis Laboratory Data by Subject: Microscopics
(Page 10 of 12)

Subject Number	Subject Classification ^a	Timepoint	Result
111	M-NS	Screening Enrollment	WBC 0-1 Neg
112	M-NS	Screening Enrollment	Neg Neg
113	M-NS	Screening Enrollment	Neg Neg
114	M-NS	Screening Enrollment	Neg Neg
115	M-NS	Screening Enrollment	Neg WBC 1-3
116	M-NS	Screening Enrollment	WBC 0-1 Neg
117	M-NS	Screening Enrollment	Neg Neg
118	M-NS	Screening Enrollment	Neg Neg
119	M-NS	Screening Enrollment	Neg Neg
120	M-NS	Screening Enrollment	Neg Neg
121	M-NS	Screening Enrollment	Neg Neg
122	M-NS	Screening Enrollment	Neg Neg
123	M-NS	Screening Enrollment	Neg Neg

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630216

Listing 16.5-30
Urinalysis Laboratory Data by Subject: Microscopies
(Page 11 of 12)

Subject Number	Subject Classification ^a	Timepoint	Result
124	M-NS	Screening Enrollment	WBC 0-1 Neg
125	M-NS	Screening Enrollment	Neg Neg
126	M-NS	Screening Enrollment	Neg Neg
127	M-NS	Screening Enrollment	Neg Neg
128	M-NS	Screening Enrollment	Neg Neg
129	M-NS	Screening Enrollment	Neg Neg
130	M-NS	Screening Enrollment	Neg Neg
131	M-NS	Screening Enrollment	Neg Neg
132	M-NS	Screening Enrollment	Neg Neg
133	M-NS	Screening Enrollment	Neg Neg
134	M-NS	Screening Enrollment	Neg WBC 2-4
135	M-NS	Screening Enrollment	Neg Neg
500	F-NS	Screening Enrollment	Bacteria RBC 0-1 Bacteria

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630217

Listing 16.5-30
Urinalysis Laboratory Data by Subject: Microscopics
(Page 12 of 12)

Subject Number	Subject Classification ^a	Timepoint	Result
501	F-NS	Screening Enrollment	Neg Neg
502	F-S	Screening Enrollment	Neg RBC 0-1
503	F-S	Screening Enrollment	Neg Neg
504	F-S	Screening Enrollment	Neg RBC 0-1
505	F-NS	Screening Enrollment	Neg RBC 0-1
506	F-S	Screening Enrollment	Neg Neg

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-31
Actual Blood and/or Plasma Collection Times by Subject
(Page 1 of 20)

Subject Number	Subject Classification ^a	Timepoint	Date	Time	Day Type
001	F-S	Week 1	09-MAY-2001	07:37	Non-Leisure
		Week 2	14-MAY-2001	07:17	Leisure
		Week 3	22-MAY-2001	07:21	Non-Leisure
		Week 6	11-JUN-2001	07:20	Leisure
002	F-S	Week 1	09-MAY-2001	06:15	Non-Leisure
		Week 2	14-MAY-2001	07:27	Leisure
		Week 3	24-MAY-2001	06:42	Non-Leisure
		Week 6	11-JUN-2001	06:17	Leisure
003	F-S	Week 1	11-MAY-2001	14:10	Leisure
		Week 2	18-MAY-2001	11:26	Leisure
		Week 3	24-MAY-2001	12:19	Leisure
		Week 6	14-JUN-2001	11:19	Non-Leisure
004	F-S	Week 1	09-MAY-2001	13:16	Leisure
		Week 2	14-MAY-2001	09:12	Leisure
		Week 3	22-MAY-2001	11:47	Non-Leisure
		Week 6	11-JUN-2001	11:45	Non-Leisure
005	F-S	Week 1	09-MAY-2001	07:52	Leisure
		Week 2	14-MAY-2001	07:41	Leisure
		Week 3	23-MAY-2001	07:31	Leisure
		Week 6	08-JUN-2001	07:15	Leisure
006	F-S	Week 1	09-MAY-2001	07:40	Non-Leisure
		Week 2	15-MAY-2001	13:10	Leisure
		Week 3	22-MAY-2001	11:24	Non-Leisure
		Week 6	12-JUN-2001	13:13	Leisure
007	F-S	Week 1	09-MAY-2001	14:35	Non-Leisure
		Week 2	17-MAY-2001	14:12	Leisure
		Week 3	25-MAY-2001	08:56	Non-Leisure
		Week 6	11-JUN-2001	08:31	Non-Leisure

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-31
Actual Blood and/or Plasma Collection Times by Subject
(Page 2 of 20)

Subject Number	Subject Classification ^a	Timepoint	Date	Time	Day Type
008	F-S	Week 1	14-MAY-2001	10:25	Leisure
		Week 2	18-MAY-2001	09:36	Leisure
		Week 3	24-MAY-2001	08:38	Non-Leisure
		Week 6	15-JUN-2001	10:05	Leisure
009	F-S	Week 1	09-MAY-2001	09:08	Leisure
		Week 2	14-MAY-2001	12:58	Leisure
		Week 3	21-MAY-2001	12:59	Non-Leisure
		Week 6	11-JUN-2001	13:00	Leisure
010	F-S	Week 1	11-MAY-2001	15:10	Non-Leisure
		Week 2	15-MAY-2001	15:22	Leisure
011	F-S	Week 1	09-MAY-2001	05:58	Non-Leisure
		Week 2	20-MAY-2001	13:02	Leisure
		Week 3	25-MAY-2001	09:28	Non-Leisure
		Week 6	17-JUN-2001	11:22	Leisure
012	F-S	Week 1	09-MAY-2001	06:09	Leisure
		Week 2	16-MAY-2001	12:27	Leisure
		Week 3	24-MAY-2001	10:44	Non-Leisure
		Week 6	16-JUN-2001	11:17	Non-Leisure
013	F-S	Week 1	09-MAY-2001	08:41	Non-Leisure
		Week 2	14-MAY-2001	08:59	Leisure
		Week 3	21-MAY-2001	09:15	Non-Leisure
		Week 6	11-JUN-2001	08:55	Leisure
014	F-S	Week 1	09-MAY-2001	08:31	Non-Leisure
		Week 2	14-MAY-2001	08:08	Leisure
		Week 3	21-MAY-2001	08:25	Non-Leisure
		Week 6	11-JUN-2001	08:39	Non-Leisure

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-31
Actual Blood and/or Plasma Collection Times by Subject
(Page 3 of 20)

Subject Number	Subject Classification ^a	Timepoint	Date	Time	Day Type
015	F-S	Week 1	09-MAY-2001	10:52	Leisure
		Week 2	14-MAY-2001	10:33	Leisure
		Week 3	21-MAY-2001	12:28	Non-Leisure
		Week 6	11-JUN-2001	12:20	Non-Leisure
016	F-S	Week 1	09-MAY-2001	07:20	Non-Leisure
		Week 2	15-MAY-2001	12:05	Leisure
		Week 3	22-MAY-2001	12:13	Non-Leisure
		Week 6	11-JUN-2001	11:56	Non-Leisure
017	F-S	Week 1	09-MAY-2001	09:21	Non-Leisure
		Week 2	25-MAY-2001	08:42	Non-Leisure
		Week 3	30-MAY-2001	08:44	Non-Leisure
		Week 6	14-JUN-2001	09:11	Leisure
018	F-S	Week 1	09-MAY-2001	07:13	Non-Leisure
		Week 2	15-MAY-2001	07:13	Leisure
		Week 3	22-MAY-2001	07:35	Non-Leisure
		Week 6	12-JUN-2001	11:53	Leisure
019	F-S	Week 1	11-MAY-2001	13:08	Non-Leisure
		Week 2	17-MAY-2001	06:59	Leisure
		Week 3	22-MAY-2001	07:27	Leisure
		Week 6	13-JUN-2001	09:43	Non-Leisure
020	F-S	Week 1	09-MAY-2001	10:57	Non-Leisure
		Week 2	16-MAY-2001	10:57	Leisure
		Week 3	23-MAY-2001	10:52	Leisure
		Week 6	13-JUN-2001	11:00	Non-Leisure
021	F-S	Week 1	10-MAY-2001	14:24	Non-Leisure
		Week 2	14-MAY-2001	15:03	Leisure
		Week 3	24-MAY-2001	14:47	Non-Leisure
		Week 6	17-JUN-2001	11:27	Leisure

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-31
Actual Blood and/or Plasma Collection Times by Subject
(Page 4 of 20)

Subject Number	Subject Classification ^a	Timepoint	Date	Time	Day Type
022	F-S	Week 1	10-MAY-2001	06:31	Leisure
		Week 2	17-MAY-2001	06:25	Leisure
		Week 3	24-MAY-2001	06:18	Non-Leisure
		Week 6	12-JUN-2001	06:23	Non-Leisure
023	F-S	Week 1	10-MAY-2001	06:45	Non-Leisure
		Week 2	17-MAY-2001	07:12	Leisure
		Week 3	24-MAY-2001	06:51	Non-Leisure
		Week 6	11-JUN-2001	15:55	Non-Leisure
024	F-S	Week 1	11-MAY-2001	07:23	Non-Leisure
		Week 2	18-MAY-2001	07:07	Leisure
		Week 3	25-MAY-2001	08:29	Non-Leisure
		Week 6	13-JUN-2001	07:18	Leisure
025	F-S	Week 1	10-MAY-2001	11:12	Non-Leisure
		Week 2	20-MAY-2001	11:35	Leisure
		Week 3	25-MAY-2001	11:49	Non-Leisure
		Week 6	17-JUN-2001	11:50	Leisure
026	F-S	Week 1	11-MAY-2001	11:20	Leisure
		Week 2	14-MAY-2001	10:40	Leisure
		Week 3	24-MAY-2001	11:17	Non-Leisure
		Week 6	16-JUN-2001	11:26	Leisure
027	F-S	Week 1	11-MAY-2001	08:48	Non-Leisure
		Week 2	16-MAY-2001	10:46	Leisure
		Week 3	21-MAY-2001	09:26	Non-Leisure
		Week 6	13-JUN-2001	11:17	Leisure
028	F-S	Week 1	11-MAY-2001	09:20	Non-Leisure
		Week 2	17-MAY-2001	09:17	Leisure
		Week 3	24-MAY-2001	09:14	Leisure
		Week 6	12-JUN-2001	09:28	Leisure

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-31
Actual Blood and/or Plasma Collection Times by Subject
(Page 5 of 20)

Subject Number	Subject Classification ^a	Timepoint	Date	Time	Day Type
029	F-S	Week 1	11-MAY-2001	07:32	Non-Leisure
		Week 2	16-MAY-2001	09:18	Leisure
		Week 3	21-MAY-2001	10:01	Leisure
		Week 6	15-JUN-2001	10:20	Non-Leisure
030	F-S	Week 1	10-MAY-2001	10:55	Non-Leisure
		Week 2	14-MAY-2001	06:58	Leisure
		Week 3	21-MAY-2001	07:21	Leisure
		Week 6	12-JUN-2001	06:47	Non-Leisure
031	F-S	Week 1	10-MAY-2001	11:28	Non-Leisure
		Week 2	15-MAY-2001	07:51	Leisure
		Week 3	23-MAY-2001	08:47	Non-Leisure
		Week 6	15-JUN-2001	10:12	Leisure
032	F-S	Week 1	11-MAY-2001	15:03	Leisure
		Week 2	20-MAY-2001	10:03	Leisure
		Week 3	25-MAY-2001	09:01	Non-Leisure
		Week 6	18-JUN-2001	06:15	Leisure
033	F-S	Week 1	11-MAY-2001	10:28	Non-Leisure
		Week 2	15-MAY-2001	08:53	Leisure
		Week 3	22-MAY-2001	08:22	Non-Leisure
		Week 6	18-JUN-2001	08:18	Leisure
034	F-S	Week 1	11-MAY-2001	15:14	Non-Leisure
		Week 2	20-MAY-2001	09:30	Leisure
		Week 3	30-MAY-2001	08:36	Non-Leisure
		Week 6	18-JUN-2001	12:27	Leisure
035	F-S	Week 1	10-MAY-2001	05:21	Leisure
		Week 2	16-MAY-2001	05:47	Leisure
		Week 3	22-MAY-2001	06:22	Non-Leisure
		Week 6	13-JUN-2001	06:10	Leisure

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-31
Actual Blood and/or Plasma Collection Times by Subject
(Page 6 of 20)

Subject Number	Subject Classification ^a	Timepoint	Date	Time	Day Type
036	M-S	Week 1	09-MAY-2001	07:03	Leisure
		Week 2	15-MAY-2001	07:24	Leisure
		Week 3	22-MAY-2001	06:44	Non-Leisure
		Week 6	11-JUN-2001	06:40	Non-Leisure
037	M-S	Week 1	10-MAY-2001	10:14	Non-Leisure
		Week 2	16-MAY-2001	06:28	Leisure
		Week 3	22-MAY-2001	09:33	Non-Leisure
		Week 6	13-JUN-2001	11:31	Leisure
038	M-S	Week 1	09-MAY-2001	09:18	Leisure
		Week 2	14-MAY-2001	09:06	Leisure
		Week 3	21-MAY-2001	09:06	Non-Leisure
		Week 6	11-JUN-2001	09:02	Non-Leisure
039	M-S	Week 1	09-MAY-2001		Leisure
		Week 1	09-MAY-2001	06:52	Leisure
		Week 2	14-MAY-2001	06:40	Leisure
		Week 3	21-MAY-2001	06:55	Non-Leisure
		Week 6	11-JUN-2001	06:33	Non-Leisure
040	M-S	Week 1	16-MAY-2001	09:41	Leisure
		Week 2	20-MAY-2001	08:25	Leisure
		Week 3	24-MAY-2001	13:16	Non-Leisure
		Week 6	17-JUN-2001	08:34	Non-Leisure
041	M-S	Week 1	11-MAY-2001	14:48	Non-Leisure
		Week 2	14-MAY-2001	09:51	Leisure
		Week 3	21-MAY-2001	14:41	Leisure
		Week 6	13-JUN-2001	09:18	Non-Leisure
042	M-S	Week 1	10-MAY-2001	12:05	Non-Leisure
		Week 2	14-MAY-2001	13:08	Leisure
		Week 3	24-MAY-2001	12:05	Non-Leisure
		Week 6	11-JUN-2001	12:01	Non-Leisure

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-31
Actual Blood and/or Plasma Collection Times by Subject
(Page 7 of 20)

Subject Number	Subject Classification ^a	Timepoint	Date	Time	Day Type
043	M-S	Week 1	09-MAY-2001	09:46	Non-Leisure
		Week 2	14-MAY-2001	09:56	Leisure
		Week 3	23-MAY-2001	09:36	Non-Leisure
		Week 6	11-JUN-2001	09:30	Leisure
044	M-S	Week 1	09-MAY-2001	12:34	Non-Leisure
		Week 2	17-MAY-2001	12:33	Leisure
		Week 3	23-MAY-2001	12:23	Non-Leisure
		Week 6	14-JUN-2001	11:35	Leisure
045	M-S	Week 1	10-MAY-2001	14:57	Leisure
		Week 2	17-MAY-2001	12:27	Leisure
		Week 3	24-MAY-2001	12:45	Leisure
		Week 6	11-JUN-2001	15:03	Non-Leisure
046	M-S	Week 1	11-MAY-2001	09:29	Leisure
		Week 2	14-MAY-2001	09:38	Leisure
		Week 3	21-MAY-2001	09:19	Non-Leisure
		Week 6	12-JUN-2001	09:41	Non-Leisure
047	M-S	Week 1	10-MAY-2001	14:54	Leisure
		Week 2	16-MAY-2001	10:13	Leisure
		Week 3	23-MAY-2001	10:15	Non-Leisure
		Week 6	13-JUN-2001	10:17	Leisure
048	M-S	Week 1	10-MAY-2001	09:30	Non-Leisure
		Week 2	16-MAY-2001	09:23	Leisure
		Week 3	21-MAY-2001	13:25	Non-Leisure
		Week 6	12-JUN-2001	09:35	Leisure
049	M-S	Week 1	11-MAY-2001	06:40	Non-Leisure
		Week 2	15-MAY-2001	08:39	Leisure
		Week 3	23-MAY-2001	08:34	Leisure
		Week 6	11-JUN-2001	09:05	Non-Leisure

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.3-31
Actual Blood and/or Plasma Collection Times by Subject
(Page 8 of 20)

Subject Number	Subject Classification ^a	Timepoint	Date	Time	Day Type
050	M-S	Week 1	11-MAY-2001	07:29	Non-Leisure
		Week 2	14-MAY-2001	08:24	Leisure
		Week 3	23-MAY-2001	07:08	Non-Leisure
		Week 6	18-JUN-2001	06:46	Leisure
052	M-S	Week 1	11-MAY-2001	10:11	Leisure
		Week 2	18-MAY-2001	10:21	Leisure
		Week 3	24-MAY-2001	12:13	Non-Leisure
		Week 6	12-JUN-2001	12:10	Non-Leisure
054	M-S	Week 1	10-MAY-2001	10:38	Non-Leisure
		Week 2	16-MAY-2001	05:53	Leisure
		Week 3	23-MAY-2001	11:22	Non-Leisure
		Week 6	13-JUN-2001	11:57	Leisure
055	M-S	Week 1	10-MAY-2001	09:23	Non-Leisure
		Week 2	15-MAY-2001	07:05	Leisure
		Week 3	23-MAY-2001	07:14	Non-Leisure
		Week 6	13-JUN-2001	07:00	Leisure
056	M-S	Week 1	11-MAY-2001	10:40	Non-Leisure
		Week 2	20-MAY-2001	06:35	Leisure
		Week 3	25-MAY-2001	06:49	Non-Leisure
		Week 6	16-JUN-2001	08:11	Non-Leisure
057	M-S	Week 1	10-MAY-2001	08:08	Non-Leisure
		Week 2	15-MAY-2001	14:03	Leisure
		Week 3	21-MAY-2001	14:03	Non-Leisure
		Week 6	17-JUN-2001	12:14	Non-Leisure
058	M-S	Week 1	11-MAY-2001	10:18	Leisure
		Week 2	20-MAY-2001	12:18	Leisure
		Week 3	25-MAY-2001	10:22	Non-Leisure
		Week 6	18-JUN-2001	09:59	Leisure

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-31
Actual Blood and/or Plasma Collection Times by Subject
(Page 9 of 20)

Subject Number	Subject Classification ^a	Timepoint	Date	Time	Day Type
059	M-S	Week 1	10-MAY-2001	12:51	Non-Leisure
		Week 2	16-MAY-2001	07:23	Leisure
		Week 3	22-MAY-2001	08:34	Non-Leisure
		Week 6	16-JUN-2001	08:44	Non-Leisure
060	M-S	Week 1	11-MAY-2001	12:25	Non-Leisure
		Week 2	18-MAY-2001	10:56	Leisure
		Week 3	25-MAY-2001	11:58	Non-Leisure
		Week 6	14-JUN-2001	08:47	Leisure
061	M-S	Week 1	11-MAY-2001	15:21	Non-Leisure
		Week 2	17-MAY-2001	08:14	Leisure
		Week 3	23-MAY-2001	10:10	Leisure
		Week 6	14-JUN-2001	10:33	Non-Leisure
062	M-S	Week 1	11-MAY-2001	11:50	Non-Leisure
		Week 2	16-MAY-2001	12:07	Leisure
		Week 3	24-MAY-2001	11:43	Non-Leisure
		Week 6	14-JUN-2001	12:43	Leisure
063	M-S	Week 1	11-MAY-2001	08:27	Leisure
		Week 2	20-MAY-2001	10:40	Leisure
		Week 3	25-MAY-2001	07:19	Non-Leisure
		Week 6	15-JUN-2001	07:12	Non-Leisure
065	M-S	Week 1	11-MAY-2001	12:55	Non-Leisure
		Week 2	17-MAY-2001	08:51	Leisure
		Week 3	22-MAY-2001	11:53	Leisure
		Week 6	16-JUN-2001	10:13	Non-Leisure
067	M-S	Week 1	11-MAY-2001	11:59	Non-Leisure
		Week 2	17-MAY-2001	07:43	Leisure
		Week 3	24-MAY-2001	10:00	Non-Leisure
		Week 6	15-JUN-2001	10:45	Leisure

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-31
Actual Blood and/or Plasma Collection Times by Subject
(Page 10 of 20)

Subject Number	Subject Classification ^a	Timepoint	Date	Time	Day Type
068	M-S	Week 1	11-MAY-2001	11:30	Non-Leisure
		Week 2	20-MAY-2001	11:05	Leisure
		Week 3	25-MAY-2001	10:13	Non-Leisure
		Week 6	17-JUN-2001	08:58	Leisure
069	M-S	Week 1	15-MAY-2001	10:23	Leisure
		Week 2	22-MAY-2001	13:25	Leisure
		Week 3	04-JUN-2001	11:35	Non-Leisure
		Week 6	13-JUN-2001	06:10	Non-Leisure
071	F-NS	Week 1	11-MAY-2001	11:00	Leisure
		Week 2	18-MAY-2001	08:55	Leisure
		Week 3	22-MAY-2001	07:21	Non-Leisure
		Week 6	12-JUN-2001	08:48	Non-Leisure
072	F-NS	Week 1	09-MAY-2001	13:02	Leisure
		Week 2	14-MAY-2001	07:09	Leisure
		Week 3	22-MAY-2001	08:27	Non-Leisure
		Week 6	12-JUN-2001	07:15	Non-Leisure
073	F-NS	Week 1	09-MAY-2001	07:28	Leisure
		Week 2	18-MAY-2001	10:30	Leisure
		Week 3	22-MAY-2001	10:18	Non-Leisure
		Week 6	13-JUN-2001	06:18	Non-Leisure
074	F-NS	Week 1	09-MAY-2001	08:19	Non-Leisure
		Week 2	14-MAY-2001	09:19	Leisure
		Week 3	22-MAY-2001	11:13	Non-Leisure
		Week 6	11-JUN-2001	07:29	Leisure
075	F-NS	Week 1	09-MAY-2001	07:46	Non-Leisure
		Week 2	14-MAY-2001	14:12	Leisure
		Week 3	23-MAY-2001	08:32	Non-Leisure
		Week 6	14-JUN-2001	08:07	Leisure

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-31
Actual Blood and/or Plasma Collection Times by Subject
(Page 11 of 20)

Subject Number	Subject Classification ^a	Timepoint	Date	Time	Day Type
076	F-NS	Week 1	11-MAY-2001	16:23	Non-Leisure
		Week 2	20-MAY-2001	12:24	Leisure
		Week 3	25-MAY-2001	12:28	Non-Leisure
		Week 6	11-JUN-2001	14:58	Leisure
077	F-NS	Week 1	09-MAY-2001	08:54	Non-Leisure
		Week 2	14-MAY-2001	08:36	Leisure
		Week 3	21-MAY-2001	08:43	Non-Leisure
		Week 6	11-JUN-2001	08:12	Leisure
078	F-NS	Week 1	10-MAY-2001	12:57	Non-Leisure
		Week 2	14-MAY-2001	14:31	Leisure
		Week 3	21-MAY-2001	13:05	Leisure
		Week 6	13-JUN-2001	11:21	Non-Leisure
079	F-NS	Week 1	09-MAY-2001	12:42	Non-Leisure
		Week 2	14-MAY-2001	11:53	Leisure
		Week 3	21-MAY-2001	12:00	Leisure
		Week 6	11-JUN-2001	12:10	Non-Leisure
080	F-NS	Week 1	09-MAY-2001	06:42	Leisure
		Week 2	15-MAY-2001	07:18	Leisure
		Week 3	21-MAY-2001	07:13	Non-Leisure
		Week 6	11-JUN-2001	06:31	Non-Leisure
081	F-NS	Week 1	09-MAY-2001	13:43	Non-Leisure
		Week 2	14-MAY-2001	13:27	Leisure
		Week 3	22-MAY-2001	13:19	Non-Leisure
		Week 6	11-JUN-2001	13:30	Leisure
082	F-NS	Week 1	09-MAY-2001	05:38	Non-Leisure
		Week 2	20-MAY-2001	11:22	Non-Leisure
		Week 3	25-MAY-2001	06:13	Non-Leisure
		Week 6	18-JUN-2001	06:38	Leisure

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-31
Actual Blood and/or Plasma Collection Times by Subject
(Page 12 of 20)

Subject Number	Subject Classification ^a	Timepoint	Date	Time	Day Type
083	F-NS	Week 1	10-MAY-2001	06:57	Non-Leisure
		Week 2	15-MAY-2001	06:57	Leisure
		Week 3	25-MAY-2001	09:44	Non-Leisure
		Week 6	12-JUN-2001	07:23	Leisure
084	F-NS	Week 1	09-MAY-2001	10:13	Non-Leisure
		Week 2	14-MAY-2001	10:06	Leisure
		Week 3	23-MAY-2001	09:57	Non-Leisure
		Week 6	13-JUN-2001	10:12	Leisure
085	F-NS	Week 1	10-MAY-2001	10:31	Non-Leisure
		Week 2	16-MAY-2001	10:37	Leisure
		Week 3	23-MAY-2001	11:13	Leisure
		Week 6	11-JUN-2001	11:52	Non-Leisure
086	F-NS	Week 1	10-MAY-2001	12:28	Leisure
		Week 2	15-MAY-2001	07:30	Leisure
		Week 3	25-MAY-2001	11:11	Non-Leisure
		Week 6	12-JUN-2001	06:42	Non-Leisure
087	F-NS	Week 1	10-MAY-2001	10:05	Non-Leisure
		Week 2	15-MAY-2001	08:00	Leisure
		Week 3	22-MAY-2001	09:52	Non-Leisure
		Week 6	11-JUN-2001	08:51	Leisure
088	F-NS	Week 1	09-MAY-2001	07:21	Non-Leisure
		Week 2	14-MAY-2001	08:16	Leisure
		Week 3	23-MAY-2001	07:23	Non-Leisure
		Week 6	11-JUN-2001	07:10	Leisure
089	F-NS	Week 1	10-MAY-2001	08:48	Non-Leisure
		Week 2	16-MAY-2001	07:50	Leisure
		Week 3	22-MAY-2001	08:37	Non-Leisure
		Week 6	11-JUN-2001	14:30	Leisure

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-31
Actual Blood and/or Plasma Collection Times by Subject
(Page 13 of 20)

Subject Number	Subject Classification ^a	Timepoint	Date	Time	Day Type
090	F-NS	Week 1	10-MAY-2001	08:25	Non-Leisure
		Week 2	14-MAY-2001	08:49	Leisure
		Week 3	24-MAY-2001	08:30	Non-Leisure
		Week 6	12-JUN-2001	09:03	Non-Leisure
091	F-NS	Week 1	10-MAY-2001	08:35	Non-Leisure
		Week 2	15-MAY-2001	08:46	Leisure
		Week 3	22-MAY-2001	08:49	Leisure
		Week 6	12-JUN-2001	08:55	Non-Leisure
092	F-NS	Week 1	10-MAY-2001	09:13	Non-Leisure
		Week 2	15-MAY-2001	09:07	Leisure
		Week 3	21-MAY-2001	08:54	Leisure
		Week 6	14-JUN-2001	07:39	Non-Leisure
093	F-NS	Week 1	10-MAY-2001	10:47	Non-Leisure
		Week 2	16-MAY-2001	10:51	Leisure
		Week 3	22-MAY-2001	10:57	Non-Leisure
		Week 6	13-JUN-2001	10:54	Leisure
094	F-NS	Week 1	10-MAY-2001	07:17	Non-Leisure
		Week 2	16-MAY-2001	09:52	Leisure
		Week 3	21-MAY-2001	10:22	Non-Leisure
		Week 6	13-JUN-2001	09:27	Non-Leisure
095	F-NS	Week 1	09-MAY-2001	13:27	Leisure
		Week 2	15-MAY-2001	11:33	Leisure
		Week 3	23-MAY-2001	14:45	Leisure
		Week 6	12-JUN-2001	11:38	Non-Leisure
096	F-NS	Week 1	11-MAY-2001	13:20	Leisure
		Week 2	15-MAY-2001	13:23	Leisure
		Week 3	21-MAY-2001	13:19	Non-Leisure
		Week 6	17-JUN-2001	09:28	Non-Leisure

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-31
Actual Blood and/or Plasma Collection Times by Subject
(Page 14 of 20)

Subject Number	Subject Classification ^a	Timepoint	Date	Time	Day Type
097	F-NS	Week 1	11-MAY-2001	09:56	Non-Leisure
		Week 2	20-MAY-2001	09:19	Leisure
		Week 3	25-MAY-2001	09:36	Non-Leisure
		Week 6	16-JUN-2001	09:15	Leisure
098	F-NS	Week 1	09-MAY-2001	15:46	Non-Leisure
		Week 2	15-MAY-2001	15:13	Leisure
		Week 3	24-MAY-2001	15:16	Non-Leisure
		Week 6	11 JUN 2001	15:10	Non Leisure
099	F-NS	Week 1	09-MAY-2001	14:05	Non-Leisure
		Week 2	14-MAY-2001	07:21	Leisure
		Week 3	22-MAY-2001	11:43	Non-Leisure
		Week 6	11-JUN-2001	10:07	Leisure
100	F-NS	Week 1	10-MAY-2001	06:36	Non-Leisure
		Week 2	18-MAY-2001	06:28	Leisure
		Week 3	23-MAY-2001	06:23	Non-Leisure
		Week 6	14-JUN-2001	06:27	Leisure
101	F-NS	Week 1	11-MAY-2001	06:29	Non-Leisure
		Week 2	14-MAY-2001	06:31	Leisure
		Week 3	25-MAY-2001	06:44	Non-Leisure
		Week 6	17-JUN-2001	09:51	Leisure
102	F-NS	Week 1	09-MAY-2001	14:23	Non-Leisure
		Week 2	20-MAY-2001	11:46	Unknown
		Week 3	25-MAY-2001	10:29	Leisure
		Week 6	12 JUN 2001	07:50	Non-Leisure
103	F-NS	Week 1	10-MAY-2001	08:11	Non-Leisure
		Week 2	20-MAY-2001	12:46	Leisure
		Week 3	24-MAY-2001	08:57	Non-Leisure
		Week 6	18-JUN-2001	09:14	Leisure

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS= Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-31
Actual Blood and/or Plasma Collection Times by Subject
(Page 15 of 20)

Subject Number	Subject Classification ^a	Timepoint	Date	Time	Day Type
104	M-NS	Week 1	07-MAY-2001	09:33	Non-Leisure
		Week 2	17-MAY-2001	07:49	Leisure
		Week 3	22-MAY-2001	07:01	Non-Leisure
		Week 6	11-JUN-2001	08:00	Leisure
105	M-NS	Week 1	09-MAY-2001	15:23	Non-Leisure
		Week 2	16-MAY-2001	09:05	Leisure
		Week 3	23-MAY-2001	06:13	Non-Leisure
		Week 6	14-JUN-2001	06:11	Leisure
106	M-NS	Week 1	11-MAY-2001	13:31	Leisure
		Week 2	18-MAY-2001	07:11	Leisure
		Week 3	23-MAY-2001	08:10	Non-Leisure
		Week 6	11-JUN-2001	07:45	Non-Leisure
107	M-NS	Week 1	11-MAY-2001	06:48	Non-Leisure
		Week 2	17-MAY-2001	07:19	Leisure
		Week 3	23-MAY-2001	07:00	Non-Leisure
		Week 6	16-JUN-2001	11:06	Leisure
108	M-NS	Week 1	09-MAY-2001	12:13	Leisure
		Week 2	14-MAY-2001	11:58	Leisure
		Week 3	21-MAY-2001	12:12	Non-Leisure
		Week 6	13-JUN-2001	12:12	Non-Leisure
109	M-NS	Week 1	09-MAY-2001	09:05	Leisure
		Week 2	14-MAY-2001	08:43	Leisure
		Week 3	21-MAY-2001	08:48	Leisure
		Week 6	11 JUN 2001	08:18	Leisure
110	M-NS	Week 1	10-MAY-2001	08:31	Non-Leisure
		Week 2	18-MAY-2001	08:38	Leisure
		Week 3	22-MAY-2001	08:17	Leisure
		Week 6	12-JUN-2001	08:22	Non-Leisure

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-31
Actual Blood and/or Plasma Collection Times by Subject
(Page 16 of 20)

Subject Number	Subject Classification ^a	Timepoint	Date	Time	Day Type
111	M-NS	Week 1	09-MAY-2001	06:51	Non-Leisure
		Week 2	14-MAY-2001	06:46	Leisure
		Week 3	21-MAY-2001	07:10	Non-Leisure
		Week 6	11-JUN-2001	06:40	Leisure
112	M-NS	Week 1	11-MAY-2001	07:22	Leisure
		Week 2	15-MAY-2001	07:45	Leisure
		Week 3	21-MAY-2001	07:55	Non-Leisure
		Week 6	11-JUN-2001	07:53	Leisure
113	M-NS	Week 1	11-MAY-2001	07:14	Non-Leisure
		Week 2	15-MAY-2001	07:40	Leisure
114	M-NS	Week 1	11-MAY-2001	11:44	Non-Leisure
		Week 2	20-MAY-2001	07:26	Leisure
		Week 3	24-MAY-2001	10:33	Non-Leisure
		Week 6	14-JUN-2001	10:23	Leisure
115	M-NS	Week 1	09-MAY-2001	10:33	Non-Leisure
		Week 2	18-MAY-2001	10:45	Leisure
		Week 3	22-MAY-2001	10:45	Non-Leisure
		Week 6	15-JUN-2001	09:43	Leisure
116	M-NS	Week 1	09-MAY-2001	07:02	Non-Leisure
		Week 2	15-MAY-2001	13:56	Leisure
		Week 3	21-MAY-2001	06:18	Non-Leisure
		Week 6	08-JUN-2001	06:15	Leisure
117	M-NS	Week 1	09-MAY-2001	11:36	Non-Leisure
		Week 2	16-MAY-2001	11:49	Leisure
		Week 3	22-MAY-2001	14:00	Leisure
		Week 6	13-JUN-2001	06:47	Leisure

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-31
Actual Blood and/or Plasma Collection Times by Subject
(Page 17 of 20)

Subject Number	Subject Classification ^a	Timepoint	Date	Time	Day Type
118	M-NS	Week 1	10-MAY-2001	13:14	Non-Leisure
		Week 2	15-MAY-2001	13:39	Leisure
		Week 3	24-MAY-2001	12:03	Leisure
		Week 6	12-JUN-2001	12:43	Leisure
119	M-NS	Week 1	09-MAY-2001	12:01	Non-Leisure
		Week 2	14-MAY-2001	11:46	Leisure
		Week 3	21-MAY-2001	11:55	Leisure
		Week 6	12-JUN-2001	12:00	Leisure
120	M-NS	Week 1	09-MAY-2001	09:14	Non-Leisure
		Week 2	14-MAY-2001	09:32	Leisure
		Week 3	23-MAY-2001	09:27	Non-Leisure
		Week 6	11-JUN-2001	09:10	Leisure
121	M-NS	Week 1	09-MAY-2001	11:21	Non-Leisure
		Week 2	14-MAY-2001	11:07	Leisure
		Week 3	22-MAY-2001	11:03	Non-Leisure
		Week 6	11-JUN-2001	11:00	Leisure
122	M-NS	Week 1	10-MAY-2001	13:37	Non-Leisure
		Week 2	14-MAY-2001	11:34	Leisure
		Week 3	21-MAY-2001	11:44	Non-Leisure
		Week 6	13-JUN-2001	11:39	Leisure
123	M-NS	Week 1	11-MAY-2001	05:55	Non-Leisure
		Week 2	15-MAY-2001	05:59	Leisure
		Week 3	23-MAY-2001	09:00	Leisure
		Week 6	12-JUN-2001	09:09	Non-Leisure
124	M-NS	Week 1	10-MAY-2001	11:44	Leisure
		Week 2	15-MAY-2001	12:13	Leisure
		Week 3	22-MAY-2001	12:22	Non-Leisure
		Week 6	13-JUN-2001	12:29	Non-Leisure

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-31
Actual Blood and/or Plasma Collection Times by Subject
(Page 18 of 20)

Subject Number	Subject Classification ^a	Timepoint	Date	Time	Day Type
125	M-NS	Week 1	09-MAY-2001	13:53	Non-Leisure
		Week 2	16-MAY-2001	08:50	Leisure
		Week 3	23-MAY-2001	15:04	Non-Leisure
		Week 6	18-JUN-2001	09:33	Leisure
126	M-NS	Week 1	09-MAY-2001	13:31	Non-Leisure
		Week 2	15-MAY-2001	11:40	Leisure
		Week 3	23-MAY-2001	14:54	Leisure
		Week 6	12-JUN-2001	11:45	Non-Leisure
127	M-NS	Week 1	11-MAY-2001	10:51	Non-Leisure
		Week 2	14-MAY-2001	13:13	Leisure
		Week 3	23-MAY-2001	09:24	Non-Leisure
		Week 6	11-JUN-2001	13:15	Leisure
128	M-NS	Week 1	10-MAY-2001	13:28	Non-Leisure
		Week 2	14-MAY-2001	12:38	Leisure
		Week 3	21-MAY-2001	12:34	Leisure
		Week 6	13-JUN-2001	12:50	Non-Leisure
129	M-NS	Week 1	10-MAY-2001	08:15	Non-Leisure
		Week 2	14-MAY-2001	15:10	Leisure
		Week 3	22-MAY-2001	15:02	Non-Leisure
		Week 6	11-JUN-2001	11:08	Leisure
130	M-NS	Week 1	10-MAY-2001	12:08	Leisure
		Week 2	15-MAY-2001	11:50	Leisure
		Week 3	23-MAY-2001	11:49	Non-Leisure
		Week 6	13-JUN-2001	11:51	Non-Leisure
131	M-NS	Week 1	10-MAY-2001	09:03	Non-Leisure
		Week 2	14-MAY-2001	08:03	Leisure
		Week 3	21-MAY-2001	07:45	Leisure
		Week 6	12-JUN-2001	07:56	Non-Leisure

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-31
Actual Blood and/or Plasma Collection Times by Subject
(Page 19 of 20)

Subject Number	Subject Classification ^a	Timepoint	Date	Time	Day Type
132	M-NS	Week 1	10-MAY-2001	07:39	Non-Leisure
		Week 2	18-MAY-2001	08:24	Leisure
		Week 3	24-MAY-2001	09:21	Non-Leisure
		Week 6	15-JUN-2001	08:16	Leisure
133	M-NS	Week 1	10-MAY-2001	13:47	Non-Leisure
		Week 2	16-MAY-2001	08:43	Leisure
		Week 3	23-MAY-2001	10:39	Leisure
		Week 6	14-JUN-2001	08:35	Leisure
134	M-NS	Week 1	17-MAY-2001	11:15	Non-Leisure
		Week 2	24-MAY-2001	13:26	Leisure
		Week 3	30-MAY-2001	11:23	Non-Leisure
		Week 6	18-JUN-2001	11:11	Non-Leisure
135	M-NS	Week 1	11-MAY-2001	08:40	Non-Leisure
		Week 2	17-MAY-2001	08:42	Leisure
		Week 3	23-MAY-2001	10:24	Non-Leisure
		Week 6	12-JUN-2001	14:07	Leisure
500	F-NS	Week 1	09-MAY-2001	14:27	Non-Leisure
		Week 2	14-MAY-2001	13:21	Leisure
		Week 3	22-MAY-2001	10:39	Non-Leisure
		Week 6	11-JUN-2001	12:50	Leisure
501	F-NS	Week 1	11-MAY-2001	09:00	Non-Leisure
		Week 2	15-MAY-2001	09:45	Leisure
		Week 3	23-MAY-2001	09:19	Non-Leisure
		Week 6	14-JUN-2001	08:27	Leisure
502	F-S	Week 1	14-MAY-2001	09:25	Leisure
		Week 2	20-MAY-2001	10:20	Leisure
		Week 3	24-MAY-2001	08:38	Non-Leisure
		Week 6	14-JUN-2001	08:52	Non-Leisure

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-31
Actual Blood and/or Plasma Collection Times by Subject
(Page 20 of 20)

Subject Number	Subject Classification ^a	Timepoint	Date	Time	Day Type
503	F-S	Week 1	10-MAY-2001	11:20	Non-Leisure
		Week 2	16-MAY-2001	11:43	Leisure
		Week 3	21-MAY-2001	11:26	Leisure
		Week 6	11-JUN-2001	10:27	Leisure
504	F-S	Week 1	11-MAY-2001	12:47	Non-Leisure
		Week 2	15-MAY-2001	12:34	Leisure
		Week 3	24-MAY-2001	12:32	Non-Leisure
		Week 6	12-JUN-2001	12:25	Leisure
505	F-NS	Week 1	11-MAY-2001	05:42	Leisure
		Week 2	18-MAY-2001	06:33	Leisure
		Week 3	25-MAY-2001	06:59	Non-Leisure
		Week 6	12-JUN-2001	06:32	Non-Leisure
506	F-S	Week 1	11-MAY-2001	13:08	Non-Leisure
		Week 2	17-MAY-2001	13:19	Non-Leisure
		Week 3	24-MAY-2001	13:12	Leisure
		Week 6	11-JUN-2001	13:10	Non-Leisure

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-32
24-Hour Urine Collection Times by Subject
(Page 1 of 16)

Subject Number	Subject Classification ^a	Timepoint	Start		Stop		Total Volume (mL)	Day Type
			Date	Time	Date	Time		
001	F-S	Week 1	08-MAY-2001	07:05	09-MAY-2001	07:45	1250	Non-Leisure
		Week 2	13-MAY-2001	07:00	14-MAY-2001	07:04	1350	Leisure
		Week 3	21-MAY-2001	07:00	22-MAY-2001	07:10	1470	Non-Leisure
002	F-S	Week 1	08-MAY-2001	06:00	09-MAY-2001	06:03	700	Non-Leisure
		Week 2	13-MAY-2001	07:15	14-MAY-2001	07:12	890	Leisure
		Week 3	23-MAY-2001	06:30	24-MAY-2001	06:30	1140	Non-Leisure
003	F-S	Week 1	10-MAY-2001	14:00	11-MAY-2001	14:03	690	Leisure
		Week 2	17-MAY-2001	11:00	18-MAY-2001	11:20	1065	Leisure
		Week 3	23-MAY-2001	12:00	24-MAY-2001	12:07	750	Leisure
004	F-S	Week 1	08-MAY-2001	14:10	09-MAY-2001	13:06	1460	Leisure
		Week 2	13-MAY-2001	09:22	14-MAY-2001	09:02	2300	Leisure
		Week 3	21-MAY-2001	12:10	22-MAY-2001	11:59	1840	Non-Leisure
005	F-S	Week 1	08-MAY-2001	07:15	09-MAY-2001	07:35	1480	Leisure
		Week 2	13-MAY-2001	07:15	14-MAY-2001	07:34	1615	Leisure
		Week 3	22-MAY-2001	06:45	23-MAY-2001	07:16	880	Leisure
006	F-S	Week 1	08-MAY-2001	07:25	09-MAY-2001	07:22	2900	Non-Leisure
		Week 2	14-MAY-2001	13:00	15-MAY-2001	13:05	3100	Leisure
		Week 3	21-MAY-2001	10:30	22-MAY-2001	11:14	2450	Non-Leisure
007	F-S	Week 1	08-MAY-2001	14:30	09-MAY-2001	14:22	870	Non-Leisure
		Week 2	16-MAY-2001	14:00	17-MAY-2001	14:04	1775	Leisure
		Week 3	24-MAY-2001	08:30	25-MAY-2001	09:17	1890	Non-Leisure
008	F-S	Week 1	13-MAY-2001	09:45	14-MAY-2001	10:09	3125	Leisure
		Week 2	17-MAY-2001	10:00	18-MAY-2001	10:00	3500	Leisure
		Week 3	23-MAY-2001	07:45	24-MAY-2001	08:22	3125	Non-Leisure
009	F-S	Week 1	08-MAY-2001	08:45	09-MAY-2001	08:54	4352	Leisure
		Week 2	13-MAY-2001	12:45	14-MAY-2001	12:50	4300	Leisure
		Week 3	20-MAY-2001	12:40	21-MAY-2001	12:54	5170	Non-Leisure

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-32
24-Hour Urine Collection Times by Subject
(Page 2 of 16)

Subject Number	Subject Classification ^a	Timepoint	Date	Start Time	Date	Stop Time	Total Volume (mL)	Day Type
010	F-S	Week 1	10-MAY-2001	02:32	11-MAY-2001	14:54	990	Non-Leisure
		Week 2	14-MAY-2001	14:58	15-MAY-2001	15:07	680	Leisure
011	F-S	Week 1	08-MAY-2001	06:00	09-MAY-2001	05:45	1470	Non-Leisure
		Week 2	19-MAY-2001	12:45	20-MAY-2001	12:55	1420	Leisure
		Week 3	24-MAY-2001	09:45	25-MAY-2001	09:40	1640	Non-Leisure
012	F-S	Week 1	08-MAY-2001	05:47	09-MAY-2001	05:54	1550	Leisure
		Week 2	15-MAY-2001	12:16	16-MAY-2001	12:15	950	Leisure
		Week 3	23-MAY-2001	10:30	24-MAY-2001	10:32	1820	Non-Leisure
013	F-S	Week 1	08-MAY-2001	08:20	09-MAY-2001	08:50	1250	Non-Leisure
		Week 2	13-MAY-2001	08:55	14-MAY-2001	08:44	1010	Leisure
		Week 3	20-MAY-2001	08:45	21-MAY-2001	09:04	730	Non-Leisure
014	F-S	Week 1	08-MAY-2001	08:05	09-MAY-2001	08:19	2005	Non-Leisure
		Week 2	13-MAY-2001	08:03	14-MAY-2001	07:58	2200	Leisure
		Week 3	20-MAY-2001	08:10	21-MAY-2001	08:16	2000	Non-Leisure
015	F-S	Week 1	08-MAY-2001	09:40	09-MAY-2001	10:29	2900	Leisure
		Week 2	13-MAY-2001	09:00	14-MAY-2001	09:00	1460	Leisure
		Week 3	20-MAY-2001	12:00	21-MAY-2001	12:19	1400	Non-Leisure
016	F-S	Week 1	08-MAY-2001	08:30	09-MAY-2001	07:10	1880	Non-Leisure
		Week 2	14-MAY-2001	12:00	15-MAY-2001	11:45	2000	Leisure
		Week 3	21-MAY-2001	13:30	22-MAY-2001	12:02	1820	Non-Leisure
017	F-S	Week 1	08-MAY-2001	09:35	09-MAY-2001	09:02	2290	Non-Leisure
		Week 2	24-MAY-2001	09:00	25-MAY-2001	08:34	2030	Non-Leisure
		Week 3	29-MAY-2001	10:00	30-MAY-2001	08:35	1930	Non-Leisure
018	F-S	Week 1	08-MAY-2001	06:05	09-MAY-2001	06:45	730	Non-Leisure
		Week 2	14-MAY-2001	07:00	15-MAY-2001	06:59	1075	Leisure
		Week 3	21-MAY-2001	07:30	22-MAY-2001	07:27	1032	Non-Leisure

^a Subject Classification: M-NS= Male, Non-Smoker; M-S= Male, Smoker; F-NS= Female, Non-Smoker; F-S= Female, Smoker.

Listing 16.5-32
24-Hour Urine Collection Times by Subject
(Page 3 of 16)

Subject Number	Subject Classification ^a	Timepoint	Date	Start Time	Date	Stop Time	Total Volume (mL)	Day Type
019	F-S	Week 1	10-MAY-2001	13:02	11-MAY-2001	12:50	2100	Non-Leisure
		Week 2	16-MAY-2001	06:50	17-MAY-2001	06:47	1210	Leisure
		Week 3	21-MAY-2001	08:00	22-MAY-2001	07:18	1840	Leisure
020	F-S	Week 1	08-MAY-2001	10:45	09-MAY-2001	10:42	3150	Non-Leisure
		Week 2	15-MAY-2001	10:45	16-MAY-2001	10:47	3500	Leisure
		Week 3	22-MAY-2001	10:45	23-MAY-2001	10:39	3150	Leisure
021	F-S	Week 1	09-MAY-2001	13:30	10-MAY-2001	14:14	880	Non-Leisure
		Week 2	13-MAY-2001	14:40	14-MAY-2001	15:28	680	Leisure
		Week 3	23-MAY-2001	14:15	24-MAY-2001	14:39	1590	Non-Leisure
022	F-S	Week 1	09-MAY-2001	05:30	10-MAY-2001	06:20	1075	Leisure
		Week 2	16-MAY-2001	06:00	17-MAY-2001	06:18	1015	Leisure
		Week 3	23-MAY-2001	06:00	24-MAY-2001	06:12	1608	Non-Leisure
023	F-S	Week 1	09-MAY-2001	05:00	10-MAY-2001	06:40	2450	Non-Leisure
		Week 2	16-MAY-2001	06:00	17-MAY-2001	07:01	1650	Leisure
		Week 3	23-MAY-2001	05:30	24-MAY-2001	06:40	1026	Non-Leisure
024	F-S	Week 1	10-MAY-2001	06:55	11-MAY-2001	07:15	2450	Non-Leisure
		Week 2	17-MAY-2001	06:45	18-MAY-2001	06:55	2200	Leisure
		Week 3	24-MAY-2001	07:00	25-MAY-2001	07:00	2925	Non-Leisure
025	F-S	Week 1	09-MAY-2001	10:00	10-MAY-2001	10:58	1280	Non-Leisure
		Week 2	19-MAY-2001	09:30	20-MAY-2001	11:30	1430	Leisure
		Week 3	24-MAY-2001	11:30	25-MAY-2001	11:41	1335	Non-Leisure
026	F-S	Week 1	10-MAY-2001	11:00	11-MAY-2001	11:08	940	Leisure
		Week 2	13-MAY-2001	10:30	14-MAY-2001	10:26	990	Leisure
		Week 3	23-MAY-2001	11:08	24-MAY-2001	11:08	1060	Non-Leisure
027	F-S	Week 1	10-MAY-2001	10:35	11-MAY-2001	08:38	2370	Non-Leisure
		Week 2	15-MAY-2001	10:50	16-MAY-2001	10:35	2520	Leisure
		Week 3	20-MAY-2001	10:30	21-MAY-2001	09:47	2295	Non-Leisure

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-32
24-Hour Urine Collection Times by Subject
(Page 4 of 16)

Subject Number	Subject Classification ^a	Timepoint	Start		Stop		Total Volume (mL)	Day Type
			Date	Time	Date	Time		
028	F-S	Week 1	10-MAY-2001	09:15	11-MAY-2001	09:08	1400	Non-Leisure
		Week 2	16-MAY-2001	09:15	17-MAY-2001	09:10	1360	Leisure
		Week 3	23-MAY-2001	09:15	24-MAY-2001	09:06	815	Leisure
029	F-S	Week 1	10-MAY-2001	05:30	11-MAY-2001	07:17	1610	Non-Leisure
		Week 2	15-MAY-2001	08:30	16-MAY-2001	09:00	1150	Leisure
		Week 3	20-MAY-2001	10:00	21-MAY-2001	09:53	1300	Leisure
030	F-S	Week 1	09-MAY-2001	11:05	10-MAY-2001	10:38	1680	Non-Leisure
		Week 2	13-MAY-2001	07:00	14-MAY-2001	06:48	1980	Leisure
		Week 3	20-MAY-2001	07:02	21-MAY-2001	07:06	1570	Leisure
031	F-S	Week 1	09-MAY-2001	11:15	10-MAY-2001	11:15	1830	Non-Leisure
		Week 2	14-MAY-2001	07:30	15-MAY-2001	07:37	2425	Leisure
		Week 3	22-MAY-2001	08:30	23-MAY-2001	08:29	1560	Non-Leisure
032	F-S	Week 1	10-MAY-2001	14:25	11-MAY-2001	14:45	2450	Leisure
		Week 2	19-MAY-2001	09:45	20-MAY-2001	09:50	2150	Leisure
		Week 3	24-MAY-2001	08:45	25-MAY-2001	08:51	2150	Non-Leisure
033	F-S	Week 1	10-MAY-2001	10:11	11-MAY-2001	11:01	1980	Non-Leisure
		Week 2	14-MAY-2001	08:02	15-MAY-2001	08:30	2675	Leisure
		Week 3	21-MAY-2001	07:33	22-MAY-2001	07:50	2720	Non-Leisure
034	F-S	Week 1	10-MAY-2001	14:50	11-MAY-2001	15:04	1800	Non-Leisure
		Week 2	19-MAY-2001	08:30	20-MAY-2001	08:55	1965	Leisure
		Week 3	29-MAY-2001	07:45	30-MAY-2001	08:25	1400	Non-Leisure
035	F-S	Week 1	09-MAY-2001	05:10	10-MAY-2001	05:10	2530	Leisure
		Week 2	15-MAY-2001	05:06	16-MAY-2001	05:40	3250	Leisure
		Week 3	21-MAY-2001	05:40	22-MAY-2001	05:40	3000	Non-Leisure
036	M-S	Week 1	08-MAY-2001	08:00	09-MAY-2001	06:43	2100	Leisure
		Week 2	14-MAY-2001	08:15	15-MAY-2001	07:08	2250	Leisure
		Week 3	21-MAY-2001	07:30	22-MAY-2001	07:00	1540	Non-Leisure

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-32
24-Hour Urine Collection Times by Subject
(Page 5 of 16)

Subject Number	Subject Classification ^a	Timepoint	Start		Stop		Total Volume (mL)	Day Type
			Date	Time	Date	Time		
037	M-S	Week 1	09-MAY-2001	10:15	10-MAY-2001	09:56	2130	Non-Leisure
		Week 2	15-MAY-2001	06:28	16-MAY-2001	06:21	2325	Leisure
		Week 3	21-MAY-2001	09:30	22-MAY-2001	09:31	3700	Non-Leisure
038	M-S	Week 1	08-MAY-2001	08:35	09-MAY-2001	08:59	1950	Leisure
		Week 2	13-MAY-2001	07:30	14-MAY-2001	08:53	920	Leisure
		Week 3	20-MAY-2001	09:30	21-MAY-2001	08:55	3060	Non-Leisure
039	M-S	Week 1	08-MAY-2001	07:00	09-MAY-2001	06:38	2890	Leisure
		Week 2	13-MAY-2001	07:55	14-MAY-2001	06:27	2500	Leisure
		Week 3	20-MAY-2001	06:45	21-MAY-2001	06:39	2200	Non-Leisure
040	M-S	Week 1	15-MAY-2001	08:53	16-MAY-2001	08:45	1435	Leisure
		Week 2	19-MAY-2001	08:33	20-MAY-2001	08:32	1250	Leisure
		Week 3	23-MAY-2001	13:00	24-MAY-2001	13:04	2030	Non-Leisure
041	M-S	Week 1	10-MAY-2001	14:30	11-MAY-2001	14:36	870	Non-Leisure
		Week 2	13-MAY-2001	09:30	14-MAY-2001	09:30	930	Leisure
		Week 3	20-MAY-2001	14:30	21-MAY-2001	14:30	1550	Leisure
042	M-S	Week 1	09-MAY-2001	11:34	10-MAY-2001	11:39	1650	Non-Leisure
		Week 2	13-MAY-2001	12:47	14-MAY-2001	13:00	1500	Leisure
		Week 3	23-MAY-2001	11:34	24-MAY-2001	11:53	1380	Non-Leisure
043	M-S	Week 1	08-MAY-2001	11:45	09-MAY-2001	09:33	2400	Non-Leisure
		Week 2	13-MAY-2001	10:00	14-MAY-2001	09:47	1390	Leisure
		Week 3	22-MAY-2001	09:15	23-MAY-2001	09:21	1500	Non-Leisure
044	M-S	Week 1	08-MAY-2001	12:15	09-MAY-2001	12:22	3000	Non-Leisure
		Week 2	16-MAY-2001	12:15	17-MAY-2001	12:22	1350	Leisure
		Week 3	22-MAY-2001	12:15	23-MAY-2001	12:14	1940	Non-Leisure
045	M-S	Week 1	09-MAY-2001	16:45	10-MAY-2001	14:46	1450	Leisure
		Week 2	16-MAY-2001	13:00	17-MAY-2001	12:19	1200	Leisure
		Week 3	23-MAY-2001	14:32	24-MAY-2001	13:13	970	Leisure

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-32
24-Hour Urine Collection Times by Subject
(Page 6 of 16)

Subject Number	Subject Classification ^a	Timepoint	Date	Start Time	Date	Stop Time	Total Volume (mL)	Day Type
046	M-S	Week 1	10-MAY-2001	11:00	11-MAY-2001	09:18	3040	Leisure
		Week 2	13-MAY-2001	09:01	14-MAY-2001	09:25	2800	Leisure
		Week 3	20-MAY-2001	09:00	21-MAY-2001	09:02	3160	Non-Leisure
047	M-S	Week 1	09-MAY-2001	14:30	10-MAY-2001	14:41	1410	Leisure
		Week 2	15-MAY-2001	10:05	16-MAY-2001	10:07	525	Leisure
		Week 3	22-MAY-2001	10:00	23-MAY-2001	10:06	1950	Non-Leisure
048	M-S	Week 1	09-MAY-2001	09:50	10-MAY-2001	09:05	1150	Non-Leisure
		Week 2	15-MAY-2001	09:00	16-MAY-2001	09:09	1285	Leisure
		Week 3	20-MAY-2001	08:35	21-MAY-2001	09:00	710	Non-Leisure
049	M-S	Week 1	09-MAY-2001	06:30	10-MAY-2001	06:30	3280	Non-Leisure
		Week 2	14-MAY-2001	08:30	15-MAY-2001	08:19	2360	Leisure
		Week 3	22-MAY-2001	07:45	23-MAY-2001	08:26	2150	Leisure
050	M-S	Week 1	10-MAY-2001	07:00	11-MAY-2001	07:18	1410	Non-Leisure
		Week 2	13-MAY-2001	07:30	14-MAY-2001	07:30	900	Leisure
		Week 3	22-MAY-2001	07:05	23-MAY-2001	06:54	1048	Non-Leisure
052	M-S	Week 1	10-MAY-2001	09:45	11-MAY-2001	09:56	3300	Leisure
		Week 2	17-MAY-2001	09:45	18-MAY-2001	10:09	3125	Leisure
		Week 3	23-MAY-2001	09:45	24-MAY-2001	09:45	3700	Non-Leisure
054	M-S	Week 1	09-MAY-2001	10:15	10-MAY-2001	10:17	1200	Non-Leisure
		Week 2	15-MAY-2001	08:35	16-MAY-2001	05:42	1690	Leisure
		Week 3	22-MAY-2001	11:00	23-MAY-2001	11:15	950	Non-Leisure
055	M-S	Week 1	09-MAY-2001	09:36	10-MAY-2001	09:01	1610	Non-Leisure
		Week 2	14-MAY-2001	07:20	15-MAY-2001	06:50	1030	Leisure
		Week 3	22-MAY-2001	07:10	23-MAY-2001	07:00	1054	Non-Leisure
056	M-S	Week 1	10-MAY-2001	08:00	11-MAY-2001	08:00	1920	Non-Leisure
		Week 2	19-MAY-2001	06:00	20-MAY-2001	06:16	1550	Leisure
		Week 3	24-MAY-2001	08:00	25-MAY-2001	07:38	560	Non-Leisure

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-32
24-Hour Urine Collection Times by Subject
(Page 7 of 16)

Subject Number	Subject Classification ^a	Timepoint	Date	Start Time	Date	Stop Time	Total Volume (mL)	Day Type
057	M-S	Week 1	09-MAY-2001	07:45	10-MAY-2001	07:54	750	Non-Leisure
		Week 2	14-MAY-2001	14:10	15-MAY-2001	13:50	1044	Leisure
		Week 3	20-MAY-2001	14:00	21-MAY-2001	13:55	2300	Non-Leisure
058	M-S	Week 1	10-MAY-2001	10:00	11-MAY-2001	10:09	1360	Leisure
		Week 2	19-MAY-2001	12:30	20-MAY-2001	12:20	1810	Leisure
		Week 3	24-MAY-2001	10:20	25-MAY-2001	10:12	1380	Non-Leisure
059	M-S	Week 1	09-MAY-2001	17:15	10-MAY-2001	12:38	2400	Non-Leisure
		Week 2	15-MAY-2001	07:00	16-MAY-2001	07:15	3375	Leisure
		Week 3	21-MAY-2001	08:15	22-MAY-2001	08:26	2600	Non-Leisure
060	M-S	Week 1	10-MAY-2001	12:00	11-MAY-2001	12:16	2340	Non-Leisure
		Week 2	17-MAY-2001	10:28	18-MAY-2001	10:49	2875	Leisure
		Week 3	24-MAY-2001	11:35	25-MAY-2001	11:48	3150	Non-Leisure
061	M-S	Week 1	10-MAY-2001	15:15	11-MAY-2001	15:10	940	Non-Leisure
		Week 2	16-MAY-2001	08:00	17-MAY-2001	08:05	1195	Leisure
		Week 3	22-MAY-2001	09:50	23-MAY-2001	10:03	1600	Leisure
062	M-S	Week 1	10-MAY-2001	11:30	11-MAY-2001	11:27	1175	Non-Leisure
		Week 2	15-MAY-2001	11:45	16-MAY-2001	11:56	900	Leisure
		Week 3	23-MAY-2001	12:00	24-MAY-2001	11:40	3020	Non-Leisure
063	M-S	Week 1	10-MAY-2001	08:06	11-MAY-2001	08:18	2280	Leisure
		Week 2	19-MAY-2001	07:00	20-MAY-2001	07:00	1351	Leisure
		Week 3	24-MAY-2001	07:15	25-MAY-2001	07:11	1030	Non-Leisure
065	M-S	Week 1	09-MAY-2001	12:30	10-MAY-2001	12:30	2700	Non-Leisure
		Week 2	16-MAY-2001	08:20	17-MAY-2001	08:36	1925	Leisure
		Week 3	21-MAY-2001	12:15	22-MAY-2001	12:02	2300	Leisure
067	M-S	Week 1	10-MAY-2001	11:00	11-MAY-2001	11:00	1060	Non-Leisure
		Week 2	16-MAY-2001	07:20	17-MAY-2001	07:22	680	Leisure
		Week 3	23-MAY-2001	10:15	24-MAY-2001	10:15	1620	Non-Leisure

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-32
24-Hour Urine Collection Times by Subject
(Page 8 of 16)

Subject Number	Subject Classification ^a	Timepoint	Date	Start Time	Date	Stop Time	Total Volume (mL)	Day Type
068	M-S	Week 1	10-MAY-2001	12:00	11-MAY-2001	11:21	3320	Non-Leisure
		Week 2	19-MAY-2001	11:00	20-MAY-2001	11:00	2809	Leisure
		Week 3	24-MAY-2001	10:45	25-MAY-2001	10:06	2750	Non-Leisure
069	M-S	Week 1	14-MAY-2001	09:57	15-MAY-2001	10:09	2350	Leisure
		Week 2	21-MAY-2001	11:13	22-MAY-2001	13:16	1430	Leisure
		Week 3	03-JUN-2001	11:17	04-JUN-2001	11:19	3150	Non-Leisure
071	F-NS	Week 1	10-MAY-2001	10:59	11-MAY-2001	10:47	2900	Leisure
		Week 2	17-MAY-2001	09:01	18-MAY-2001	09:04	4585	Leisure
		Week 3	21-MAY-2001	07:00	22-MAY-2001	07:04	4740	Non-Leisure
072	F-NS	Week 1	08-MAY-2001	11:15	09-MAY-2001	12:41	2825	Leisure
		Week 2	13-MAY-2001	06:59	14-MAY-2001	07:00	2200	Leisure
		Week 3	21-MAY-2001	08:33	22-MAY-2001	08:15	2870	Non-Leisure
073	F-NS	Week 1	08-MAY-2001	06:00	09-MAY-2001	07:16	1510	Leisure
		Week 2	17-MAY-2001	10:45	18-MAY-2001	10:47	1695	Leisure
		Week 3	21-MAY-2001	10:00	22-MAY-2001	10:11	1670	Non-Leisure
074	F-NS	Week 1	08-MAY-2001	08:45	09-MAY-2001	08:06	2278	Non-Leisure
		Week 2	13-MAY-2001	08:45	14-MAY-2001	09:04	2200	Leisure
		Week 3	21-MAY-2001	10:00	22-MAY-2001	11:04	1470	Non-Leisure
075	F-NS	Week 1	08-MAY-2001	06:00	09-MAY-2001	06:00	1600	Non-Leisure
		Week 2	13-MAY-2001	14:30	14-MAY-2001	14:30	1240	Leisure
		Week 3	22-MAY-2001	08:25	23-MAY-2001	08:22	1068	Non-Leisure
076	F-NS	Week 1	10-MAY-2001	16:12	11-MAY-2001	16:05	800	Non-Leisure
		Week 2	19-MAY-2001	12:16	20-MAY-2001	12:10	750	Leisure
		Week 3	24-MAY-2001	12:23	25-MAY-2001	12:05	1350	Non-Leisure
077	F-NS	Week 1	08-MAY-2001	08:00	09-MAY-2001	08:43	3000	Non-Leisure
		Week 2	13-MAY-2001	07:45	14-MAY-2001	08:26	3150	Leisure
		Week 3	20-MAY-2001	07:15	21-MAY-2001	08:35	3290	Non-Leisure

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-32
24-Hour Urine Collection Times by Subject
(Page 9 of 16)

Subject Number	Subject Classification ^a	Timepoint	Date	Start Time	Date	Stop Time	Total Volume (mL)	Day Type
078	F-NS	Week 1	09-MAY-2001	13:25	10-MAY-2001	12:51	570	Non-Leisure
		Week 2	13-MAY-2001	14:37	14-MAY-2001	13:56	660	Leisure
		Week 3	20-MAY-2001	13:07	21-MAY-2001	13:00	2050	Leisure
079	F-NS	Week 1	08-MAY-2001	12:30	09-MAY-2001	12:27	1350	Non-Leisure
		Week 2	13-MAY-2001	12:00	14-MAY-2001	11:44	1370	Leisure
		Week 3	20-MAY-2001	11:55	21-MAY-2001	11:50	1690	Leisure
080	F-NS	Week 1	08-MAY-2001	06:34	09-MAY-2001	06:31	3208	Leisure
		Week 2	14-MAY-2001	06:55	15-MAY-2001	07:03	2875	Leisure
		Week 3	20-MAY-2001	06:55	21-MAY-2001	06:58	3200	Non-Leisure
081	F-NS	Week 1	08-MAY-2001	13:30	09-MAY-2001	13:21	2080	Non-Leisure
		Week 2	13-MAY-2001	13:25	14-MAY-2001	13:16	2910	Leisure
		Week 3	21-MAY-2001	13:30	22-MAY-2001	13:26	2030	Non-Leisure
082	F-NS	Week 1	08-MAY-2001	05:00	09-MAY-2001	05:28	1440	Non-Leisure
		Week 2	19-MAY-2001	10:30	20-MAY-2001	10:59	1780	Non-Leisure
		Week 3	24-MAY-2001	06:00	25-MAY-2001	06:32	1960	Non-Leisure
083	F-NS	Week 1	09-MAY-2001	06:38	10-MAY-2001	06:46	1570	Non-Leisure
		Week 2	14-MAY-2001	06:42	15-MAY-2001	06:47	1560	Leisure
		Week 3	24-MAY-2001	09:32	25-MAY-2001	09:31	2360	Non-Leisure
084	F-NS	Week 1	08-MAY-2001	10:16	09-MAY-2001	10:33	1900	Non-Leisure
		Week 2	13-MAY-2001	09:45	14-MAY-2001	09:55	1980	Leisure
		Week 3	22-MAY-2001	10:00	23-MAY-2001	09:50	2395	Non-Leisure
085	F-NS	Week 1	09-MAY-2001	10:15	10-MAY-2001	10:10	1140	Non-Leisure
		Week 2	15-MAY-2001	10:25	16-MAY-2001	10:25	1740	Leisure
		Week 3	22-MAY-2001	11:15	23-MAY-2001	11:04	1450	Leisure
086	F-NS	Week 1	09-MAY-2001	12:21	10-MAY-2001	12:16	980	Leisure
		Week 2	14-MAY-2001	07:30	15-MAY-2001	07:13	970	Leisure
		Week 3	24-MAY-2001	10:50	25-MAY-2001	11:03	990	Non-Leisure

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-32
24-Hour Urine Collection Times by Subject
(Page 10 of 16)

Subject Number	Subject Classification ^a	Timepoint	Start		Stop		Total Volume (mL)	Day Type
			Date	Time	Date	Time		
087	F-NS	Week 1	09-MAY-2001	10:15	10-MAY-2001	09:53	2120	Non-Leisure
		Week 2	14-MAY-2001	08:00	15-MAY-2001	07:51	2150	Leisure
		Week 3	21-MAY-2001	10:00	22-MAY-2001	09:44	2400	Non-Leisure
088	F-NS	Week 1	08-MAY-2001	07:00	09-MAY-2001	07:00	960	Non-Leisure
		Week 2	13-MAY-2001	08:00	14-MAY-2001	08:03	1310	Leisure
		Week 3	22-MAY-2001	07:00	23-MAY-2001	07:01	1610	Non-Leisure
089	F-NS	Week 1	09-MAY-2001	11:23	10-MAY-2001	08:38	1400	Non-Leisure
		Week 2	15-MAY-2001	09:30	16-MAY-2001	07:45	2925	Leisure
		Week 3	21-MAY-2001	08:53	22-MAY-2001	08:46	2930	Non-Leisure
090	F-NS	Week 1	09-MAY-2001	08:30	10-MAY-2001	08:14	2800	Non-Leisure
		Week 2	13-MAY-2001	09:01	14-MAY-2001	08:14	2500	Leisure
		Week 3	23-MAY-2001	08:46	24-MAY-2001	08:17	3350	Non-Leisure
091	F-NS	Week 1	09-MAY-2001	10:00	10-MAY-2001	08:23	1370	Non-Leisure
		Week 2	14-MAY-2001	08:45	15-MAY-2001	08:29	1950	Leisure
		Week 3	21-MAY-2001	08:45	22-MAY-2001	08:34	1765	Leisure
092	F-NS	Week 1	09-MAY-2001	09:15	10-MAY-2001	08:56	1850	Non-Leisure
		Week 2	14-MAY-2001	08:50	15-MAY-2001	08:57	2000	Leisure
		Week 3	20-MAY-2001	08:30	21-MAY-2001	08:41	1880	Leisure
093	F-NS	Week 1	09-MAY-2001	09:45	10-MAY-2001	11:06	3250	Non-Leisure
		Week 2	15-MAY-2001	08:50	16-MAY-2001	10:38	3400	Leisure
		Week 3	21-MAY-2001	10:05	22-MAY-2001	10:46	1880	Non-Leisure
094	F-NS	Week 1	09-MAY-2001	07:35	10-MAY-2001	06:57	1140	Non-Leisure
		Week 2	15-MAY-2001	09:30	16-MAY-2001	09:35	1280	Leisure
		Week 3	20-MAY-2001	10:30	21-MAY-2001	10:13	1200	Non-Leisure
095	F-NS	Week 1	08-MAY-2001	13:12	09-MAY-2001	13:12	1950	Leisure
		Week 2	14-MAY-2001	11:17	15-MAY-2001	11:21	2210	Leisure
		Week 3	22-MAY-2001	14:30	23-MAY-2001	14:34	2270	Leisure

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker

Listing 16.5-32
24-Hour Urine Collection Times by Subject
(Page 11 of 16)

Subject Number	Subject Classification ^a	Timepoint	Start		Stop		Total Volume (mL)	Day Type
			Date	Time	Date	Time		
096	F-NS	Week 1	10-MAY-2001	13:00	11-MAY-2001	13:00	1800	Leisure
		Week 2	14-MAY-2001	13:00	15-MAY-2001	13:16	2650	Leisure
		Week 3	20-MAY-2001	13:00	21-MAY-2001	13:10	2000	Non-Leisure
097	F-NS	Week 1	10-MAY-2001	09:31	11-MAY-2001	09:35	3350	Non-Leisure
		Week 2	19-MAY-2001	09:02	20-MAY-2001	09:08	2480	Leisure
		Week 3	24-MAY-2001	09:40	25-MAY-2001	09:23	2650	Non-Leisure
098	F-NS	Week 1	08-MAY-2001	14:45	09-MAY-2001	15:38	2725	Non-Leisure
		Week 2	14-MAY-2001	14:45	15-MAY-2001	14:55	2740	Leisure
		Week 3	23-MAY-2001	14:45	24-MAY-2001	15:10	2050	Non-Leisure
099	F-NS	Week 1	08-MAY-2001	13:30	09-MAY-2001	13:52	1360	Non-Leisure
		Week 2	13-MAY-2001	09:19	14-MAY-2001	07:05	915	Leisure
		Week 3	21-MAY-2001	11:45	22-MAY-2001	11:33	1445	Non-Leisure
100	F-NS	Week 1	09-MAY-2001	06:15	10-MAY-2001	06:22	1470	Non-Leisure
		Week 2	17-MAY-2001	06:15	18-MAY-2001	06:23	2025	Leisure
		Week 3	22-MAY-2001	06:15	23-MAY-2001	06:18	1300	Non-Leisure
101	F-NS	Week 1	10-MAY-2001	06:13	11-MAY-2001	06:13	1980	Non-Leisure
		Week 2	13-MAY-2001	06:15	14-MAY-2001	06:19	1710	Leisure
		Week 3	24-MAY-2001	06:17	25-MAY-2001	07:05	2760	Non-Leisure
102	F-NS	Week 1	08-MAY-2001	14:00	09-MAY-2001	14:09	1200	Non-Leisure
		Week 2	19-MAY-2001	11:15	20-MAY-2001	11:37	1040	Unknown
		Week 3	24-MAY-2001	10:15	25-MAY-2001	10:15	1260	Leisure
103	F-NS	Week 1	09-MAY-2001	08:01	10-MAY-2001	07:59	1350	Non-Leisure
		Week 2	19-MAY-2001	12:00	20-MAY-2001	12:32	1315	Leisure
		Week 3	23-MAY-2001	08:15	24-MAY-2001	08:54	940	Non-Leisure
104	M-NS	Week 1	06-MAY-2001	08:30	07-MAY-2001	09:24	810	Non-Leisure
		Week 2	16-MAY-2001	07:35	17-MAY-2001	07:39	1525	Leisure
		Week 3	21-MAY-2001	07:00	22-MAY-2001	06:53	1430	Non-Leisure

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-32
24-Hour Urine Collection Times by Subject
(Page 12 of 16)

Subject Number	Subject Classification ^a	Timepoint	Start		Stop		Total Volume (mL)	Day Type
			Date	Time	Date	Time		
105	M-NS	Week 1	08-MAY-2001	15:00	09-MAY-2001	15:09	2005	Non-Leisure
		Week 2	15-MAY-2001	09:00	16-MAY-2001	08:54	1275	Leisure
		Week 3	22-MAY-2001	06:00	23-MAY-2001	06:09	1170	Non-Leisure
106	M-NS	Week 1	10-MAY-2001	14:00	11-MAY-2001	14:09	1400	Leisure
		Week 2	17-MAY-2001	07:30	18-MAY-2001	07:30	2195	Leisure
		Week 3	22-MAY-2001	08:00	23-MAY-2001	07:57	1440	Non-Leisure
107	M-NS	Week 1	10-MAY-2001	06:45	11-MAY-2001	06:35	1330	Non-Leisure
		Week 2	16-MAY-2001	07:00	17-MAY-2001	07:07	1350	Leisure
		Week 3	22-MAY-2001	07:00	23-MAY-2001	06:55	1120	Non-Leisure
108	M-NS	Week 1	08-MAY-2001	12:10	09-MAY-2001	12:00	3800	Leisure
		Week 2	13-MAY-2001	12:11	14-MAY-2001	11:52	1130	Leisure
		Week 3	20-MAY-2001	12:00	21-MAY-2001	12:04	3125	Non-Leisure
109	M-NS	Week 1	08-MAY-2001	06:30	09-MAY-2001	09:12	1190	Leisure
		Week 2	13-MAY-2001	08:00	14-MAY-2001	08:34	1230	Leisure
		Week 3	20-MAY-2001	07:00	21-MAY-2001	08:37	1072	Leisure
110	M-NS	Week 1	09-MAY-2001	08:20	10-MAY-2001	08:15	880	Non-Leisure
		Week 2	17-MAY-2001	08:30	18-MAY-2001	08:30	1290	Leisure
		Week 3	21-MAY-2001	08:20	22-MAY-2001	08:21	1300	Leisure
111	M-NS	Week 1	08-MAY-2001	06:15	09-MAY-2001	06:34	1210	Non-Leisure
		Week 2	13-MAY-2001	07:00	14-MAY-2001	06:37	3200	Leisure
		Week 3	20-MAY-2001	06:00	21-MAY-2001	06:45	1590	Non-Leisure
112	M-NS	Week 1	10-MAY-2001	07:00	11-MAY-2001	07:11	1690	Leisure
		Week 2	14-MAY-2001	06:05	15-MAY-2001	07:32	1210	Leisure
		Week 3	20-MAY-2001	07:01	21-MAY-2001	07:47	2000	Non-Leisure
113	M-NS	Week 1	10-MAY-2001	08:35	11-MAY-2001	07:06	2140	Non-Leisure
		Week 2	14-MAY-2001	07:45	15-MAY-2001	07:31	2000	Leisure

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-32
24-Hour Urine Collection Times by Subject
(Page 13 of 16)

Subject Number	Subject Classification ^a	Timepoint	Date	Start Time	Date	Stop Time	Total Volume (mL)	Day Type
114	M-NS	Week 1	10-MAY-2001	11:10	11-MAY-2001	11:31	3000	Non-Leisure
		Week 2	19-MAY-2001	06:59	20-MAY-2001	07:32	2750	Leisure
		Week 3	23-MAY-2001	10:50	24-MAY-2001	10:45	2910	Non-Leisure
115	M-NS	Week 1	08-MAY-2001	10:00	09-MAY-2001	10:21	1230	Non-Leisure
		Week 2	17-MAY-2001	10:15	18-MAY-2001	10:31	820	Leisure
		Week 3	21-MAY-2001	10:15	22-MAY-2001	10:39	1350	Non-Leisure
116	M-NS	Week 1	08-MAY-2001	05:05	09-MAY-2001	06:50	650	Non-Leisure
		Week 2	14-MAY-2001	14:00	15-MAY-2001	13:45	1410	Leisure
		Week 3	20-MAY-2001	06:00	21-MAY-2001	06:01	1110	Non-Leisure
117	M-NS	Week 1	08-MAY-2001	11:50	09-MAY-2001	11:14	2220	Non-Leisure
		Week 2	15-MAY-2001	11:30	16-MAY-2001	11:37	1860	Leisure
		Week 3	21-MAY-2001	15:30	22-MAY-2001	14:19	2500	Leisure
118	M-NS	Week 1	09-MAY-2001	13:00	10-MAY-2001	13:00	2150	Non-Leisure
		Week 2	14-MAY-2001	13:30	15-MAY-2001	13:34	2175	Leisure
		Week 3	23-MAY-2001	12:00	24-MAY-2001	11:53	1660	Leisure
119	M-NS	Week 1	08-MAY-2001	13:30	09-MAY-2001	11:52	1200	Non-Leisure
		Week 2	13-MAY-2001	10:45	14-MAY-2001	11:39	1315	Leisure
		Week 3	20-MAY-2001	11:33	21-MAY-2001	11:47	2100	Leisure
120	M-NS	Week 1	08-MAY-2001	09:15	09-MAY-2001	08:57	780	Non-Leisure
		Week 2	13-MAY-2001	09:45	14-MAY-2001	09:22	830	Leisure
		Week 3	22-MAY-2001	09:30	23-MAY-2001	09:19	750	Non-Leisure
121	M-NS	Week 1	08-MAY-2001	11:30	09-MAY-2001	11:05	1500	Non-Leisure
		Week 2	13-MAY-2001	11:00	14-MAY-2001	11:00	2350	Leisure
		Week 3	21-MAY-2001	10:50	22-MAY-2001	10:54	1720	Non-Leisure
122	M-NS	Week 1	09-MAY-2001	13:15	10-MAY-2001	13:23	530	Non-Leisure
		Week 2	13-MAY-2001	11:40	14-MAY-2001	11:28	1100	Leisure
		Week 3	20-MAY-2001	11:30	21-MAY-2001	11:38	750	Non-Leisure

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-32
24-Hour Urine Collection Times by Subject
(Page 14 of 16)

Subject Number	Subject Classification ^a	Timepoint	Start		Stop		Total Volume (mL)	Day Type
			Date	Time	Date	Time		
123	M-NS	Week 1	10-MAY-2001	06:00	11-MAY-2001	05:46	1480	Non-Leisure
		Week 2	14-MAY-2001	06:04	15-MAY-2001	05:50	2900	Leisure
		Week 3	22-MAY-2001	09:06	23-MAY-2001	08:55	2900	Leisure
124	M-NS	Week 1	09-MAY-2001	11:30	10-MAY-2001	11:33	1330	Leisure
		Week 2	14-MAY-2001	12:00	15-MAY-2001	12:02	1680	Leisure
		Week 3	21-MAY-2001	12:00	22-MAY-2001	12:10	2064	Non-Leisure
125	M-NS	Week 1	08-MAY-2001	13:45	09-MAY-2001	13:38	1030	Non-Leisure
		Week 2	15-MAY-2001	08:00	16-MAY-2001	08:28	815	Leisure
		Week 3	22-MAY-2001	14:58	23-MAY-2001	14:59	1430	Non-Leisure
126	M-NS	Week 1	08-MAY-2001	13:15	09-MAY-2001	13:18	1220	Non-Leisure
		Week 2	14-MAY-2001	11:45	15-MAY-2001	11:25	1450	Leisure
		Week 3	22-MAY-2001	14:30	23-MAY-2001	14:35	1610	Leisure
127	M-NS	Week 1	10-MAY-2001	10:20	11-MAY-2001	10:35	1175	Non-Leisure
		Week 2	13-MAY-2001	12:50	14-MAY-2001	13:01	625	Leisure
		Week 3	22-MAY-2001	09:15	23-MAY-2001	09:12	1780	Non-Leisure
128	M-NS	Week 1	09-MAY-2001	13:15	10-MAY-2001	13:16	3350	Non-Leisure
		Week 2	13-MAY-2001	12:30	14-MAY-2001	12:30	4700	Leisure
		Week 3	20-MAY-2001	12:30	21-MAY-2001	12:26	4270	Leisure
129	M-NS	Week 1	09-MAY-2001	06:30	10-MAY-2001	07:59	2040	Non-Leisure
		Week 2	13-MAY-2001	15:00	14-MAY-2001	15:02	1680	Leisure
		Week 3	21-MAY-2001	14:25	22-MAY-2001	14:55	1800	Non-Leisure
130	M-NS	Week 1	09-MAY-2001	11:45	10-MAY-2001	11:42	1930	Leisure
		Week 2	14-MAY-2001	11:45	15-MAY-2001	11:43	1490	Leisure
		Week 3	22-MAY-2001	11:45	23-MAY-2001	11:41	1080	Non-Leisure
131	M-NS	Week 1	09-MAY-2001	09:00	10-MAY-2001	08:51	3200	Non-Leisure
		Week 2	13-MAY-2001	08:15	14-MAY-2001	07:57	2750	Leisure
		Week 3	20-MAY-2001	07:45	21-MAY-2001	07:37	2900	Leisure

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-32
24-Hour Urine Collection Times by Subject
(Page 15 of 16)

Subject Number	Subject Classification ^a	Timepoint	Start		Stop		Total Volume (mL)	Day Type
			Date	Time	Date	Time		
132	M-NS	Week 1	09-MAY-2001	06:45	10-MAY-2001	07:22	3300	Non-Leisure
		Week 2	17-MAY-2001	08:00	18-MAY-2001	08:00	3250	Leisure
		Week 3	23-MAY-2001	09:00	24-MAY-2001	09:10	3440	Non-Leisure
133	M-NS	Week 1	09-MAY-2001	13:30	10-MAY-2001	13:35	950	Non-Leisure
		Week 2	15-MAY-2001	08:30	16-MAY-2001	08:33	1023	Leisure
		Week 3	22-MAY-2001	10:30	23-MAY-2001	10:31	2150	Leisure
134	M-NS	Week 1	16-MAY-2001	11:05	17-MAY-2001	11:07	2790	Non-Leisure
		Week 2	23-MAY-2001	11:50	24-MAY-2001	12:30	2850	Leisure
		Week 3	29-MAY-2001	11:06	30-MAY-2001	11:14	2950	Non-Leisure
135	M-NS	Week 1	10-MAY-2001	08:00	11-MAY-2001	08:30	980	Non-Leisure
		Week 2	16-MAY-2001	08:30	17-MAY-2001	08:32	760	Leisure
		Week 3	22-MAY-2001	10:00	23-MAY-2001	10:11	2075	Non-Leisure
500	F-NS	Week 1	08-MAY-2001	16:14	09-MAY-2001	14:16	3110	Non-Leisure
		Week 2	13-MAY-2001	13:15	14-MAY-2001	13:15	2160	Leisure
		Week 3	21-MAY-2001	10:45	22-MAY-2001	10:31	2650	Non-Leisure
501	F-NS	Week 1	10-MAY-2001	08:45	11-MAY-2001	08:45	2700	Non-Leisure
		Week 2	14-MAY-2001	09:35	15-MAY-2001	09:32	2900	Leisure
		Week 3	22-MAY-2001	08:30	23-MAY-2001	09:11	2900	Non-Leisure
502	F-S	Week 1	13-MAY-2001	09:15	14-MAY-2001	09:11	1800	Leisure
		Week 2	19-MAY-2001	11:10	20-MAY-2001	10:09	1455	Leisure
		Week 3	23-MAY-2001	08:00	24-MAY-2001	08:21	2160	Non-Leisure
503	F-S	Week 1	09-MAY-2001	10:07	10-MAY-2001	11:05	1770	Non-Leisure
		Week 2	15-MAY-2001	10:30	16-MAY-2001	11:29	660	Leisure
		Week 3	20-MAY-2001	11:00	21-MAY-2001	11:09	1200	Leisure
504	F-S	Week 1	10-MAY-2001	12:15	11-MAY-2001	12:37	1700	Non-Leisure
		Week 2	14-MAY-2001	12:20	15-MAY-2001	12:23	1280	Leisure
		Week 3	23-MAY-2001	12:15	24-MAY-2001	12:23	2850	Non-Leisure

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-32
 24-Hour Urine Collection Times by Subject
 (Page 16 of 16)

Subject Number	Subject Classification ^a	Timepoint	Start		Stop		Total Volume (mL)	Day Type
			Date	Time	Date	Time		
505	F-NS	Week 1	10-MAY-2001	07:38	11-MAY-2001	05:29	2640	Leisure
		Week 2	17-MAY-2001	08:10	18-MAY-2001	08:09	3150	Leisure
		Week 3	24-MAY-2001	06:15	25-MAY-2001	06:40	2450	Non-Leisure
506	F-S	Week 1	10-MAY-2001	12:45	11-MAY-2001	12:55	2750	Non-Leisure
		Week 2	16-MAY-2001	14:00	17-MAY-2001	13:07	1825	Non-Leisure
		Week 3	23-MAY-2001	13:00	24-MAY-2001	13:02	1860	Leisure

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-33
Exhale Collection Times by Subject
(Page 1 of 20)

Subject Number	Subject Classification ^a	Timepoint	Acetonitrile		Carbon Monoxide	
			Date	Time	Date	Time
001	F-S	Week 1	09-MAY-2001	07:18	09-MAY-2001	07:22
		Week 2			14-MAY-2001	07:07
		Week 3	22-MAY-2001	07:14	22-MAY-2001	07:13
		Week 6	11-JUN-2001	07:10	11-JUN-2001	07:06
002	F-S	Week 1	09-MAY-2001	06:03	09-MAY-2001	06:05
		Week 2			14-MAY-2001	07:15
		Week 3	24-MAY-2001	06:32	24-MAY-2001	06:30
		Week 6	11-JUN-2001	06:01	11-JUN-2001	05:58
003	F-S	Week 1	11-MAY-2001	14:05	11-MAY-2001	14:05
		Week 2			18-MAY-2001	11:19
		Week 3	24-MAY-2001	12:07	24-MAY-2001	12:10
		Week 6	14-JUN-2001	11:13	14-JUN-2001	11:11
004	F-S	Week 1	09-MAY-2001	13:10	09-MAY-2001	13:11
		Week 2			14-MAY-2001	09:02
		Week 3	22-MAY-2001	11:40	22-MAY-2001	11:39
		Week 6	11-JUN-2001	11:34	11-JUN-2001	11:34
005	F-S	Week 1	09-MAY-2001	07:38	09-MAY-2001	07:40
		Week 2			14-MAY-2001	07:36
		Week 3	23-MAY-2001	07:23	23-MAY-2001	07:21
		Week 6	08-JUN-2001	07:17	08-JUN-2001	07:19
006	F-S	Week 1	09-MAY-2001	07:23	09-MAY-2001	07:27
		Week 2			15-MAY-2001	13:03
		Week 3	22-MAY-2001	11:17	22-MAY-2001	11:16
		Week 6	12-JUN-2001	13:07	12-JUN-2001	13:08
007	F-S	Week 1	09-MAY-2001	14:27	09-MAY-2001	14:28
		Week 2			17-MAY-2001	13:57
		Week 3	25-MAY-2001	08:50	25-MAY-2001	08:48
		Week 6	11-JUN-2001	08:23	11-JUN-2001	08:28

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-33
Exhale Collection Times by Subject
(Page 2 of 20)

Subject Number	Subject Classification ^a	Timepoint	Acetonitrile		Carbon Monoxide	
			Date	Time	Date	Time
008	F-S	Week 1	14-MAY-2001	10:13	14-MAY-2001	10:15
		Week 2			18-MAY-2001	09:30
		Week 3	24-MAY-2001	08:24	24-MAY-2001	08:29
		Week 6	15-JUN-2001	10:00	15-JUN-2001	09:57
009	F-S	Week 1	09-MAY-2001	08:56	09-MAY-2001	08:58
		Week 2			14-MAY-2001	12:51
		Week 3	21-MAY-2001	13:07	21-MAY-2001	13:06
		Week 6	11-JUN-2001	12:51	11-JUN-2001	12:51
010	F-S	Week 1	11-MAY-2001	14:55	11-MAY-2001	14:56
		Week 2			15-MAY-2001	15:11
011	F-S	Week 1	09-MAY-2001	05:44	09-MAY-2001	05:47
		Week 2			20-MAY-2001	12:59
		Week 3	25-MAY-2001	09:23	25-MAY-2001	09:21
		Week 6	17-JUN-2001	11:14	17-JUN-2001	11:13
012	F-S	Week 1	09-MAY-2001	05:55	09-MAY-2001	05:58
		Week 2			16-MAY-2001	13:02
		Week 3	24-MAY-2001	10:38	24-MAY-2001	10:38
		Week 6	16-JUN-2001	11:07	16-JUN-2001	11:08
013	F-S	Week 1	09-MAY-2001	08:34	09-MAY-2001	08:35
		Week 2			14-MAY-2001	08:51
		Week 3	21-MAY-2001	09:03	21-MAY-2001	09:07
		Week 6	11-JUN-2001	08:47	11-JUN-2001	08:46
014	F-S	Week 1	09-MAY-2001	08:22	09-MAY-2001	08:23
		Week 2			14-MAY-2001	08:01
		Week 3	21-MAY-2001	08:16	21-MAY-2001	08:18
		Week 6	11-JUN-2001	08:28	11-JUN-2001	08:33
015	F-S	Week 1	09-MAY-2001	10:32	09-MAY-2001	10:33
		Week 2			14-MAY-2001	10:21
		Week 3	21-MAY-2001	12:21	21-MAY-2001	12:20
		Week 6	11-JUN-2001	12:00	11-JUN-2001	12:00

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-33
Exhale Collection Times by Subject
(Page 3 of 20)

Subject Number	Subject Classification ^a	Timepoint	Acetonitrile		Carbon Monoxide	
			Date	Time	Date	Time
016	F-S	Week 1	09-MAY-2001	07:12	09-MAY-2001	12:13
		Week 2			15-MAY-2001	12:00
		Week 3	22-MAY-2001	12:06	22-MAY-2001	12:05
		Week 6	11-JUN-2001	11:47	11-JUN-2001	11:45
017	F-S	Week 1	09-MAY-2001	09:07	09-MAY-2001	09:09
		Week 2			25-MAY-2001	08:36
		Week 3	30-MAY-2001	08:37	30-MAY-2001	08:36
		Week 6	14-JUN-2001	09:02	14 JUN 2001	09:00
018	F-S	Week 1	09-MAY-2001	06:59	09-MAY-2001	07:01
		Week 2			15-MAY-2001	07:02
		Week 3	22-MAY-2001	07:32	22-MAY-2001	07:30
		Week 6	12-JUN-2001	11:44	12-JUN-2001	11:41
019	F-S	Week 1	11-MAY-2001	12:53	11-MAY-2001	12:51
		Week 2			17-MAY-2001	06:50
		Week 3	22-MAY-2001	07:23	22-MAY-2001	07:21
		Week 6	13-JUN-2001	09:37	13-JUN-2001	09:32
020	F-S	Week 1	09-MAY-2001	10:45	09-MAY-2001	10:46
		Week 2			16-MAY-2001	10:45
		Week 3	23-MAY-2001	10:41	23-MAY-2001	10:39
		Week 6	13-JUN-2001	10:50	13-JUN-2001	10:49
021	F-S	Week 1	10-MAY-2001	14:19	10-MAY-2001	14:17
		Week 2			14-MAY-2001	14:56
		Week 3	24-MAY-2001	14:41	24-MAY-2001	14:39
		Week 6	17-JUN-2001	11:18	17-JUN-2001	11:19
022	F-S	Week 1	10-MAY-2001	06:23	10-MAY-2001	06:24
		Week 2			17-MAY-2001	06:20
		Week 3	24-MAY-2001	06:08	24-MAY-2001	06:08
		Week 6	12-JUN-2001	06:15	12-JUN-2001	06:15

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-33
Exhale Collection Times by Subject
(Page 4 of 20)

Subject Number	Subject Classification ^a	Timepoint	Acetonitrile		Carbon Monoxide	
			Date	Time	Date	Time
023	F-S	Week 1	10-MAY-2001	06:39	10-MAY-2001	06:40
		Week 2			17-MAY-2001	07:04
		Week 3	24-MAY-2001	06:44	24-MAY-2001	06:44
		Week 6	11-JUN-2001	15:54	11-JUN-2001	15:52
024	F-S	Week 1	11-MAY-2001	07:17	11-MAY-2001	07:18
		Week 2			18-MAY-2001	06:55
		Week 3	25-MAY-2001	08:21	25-MAY-2001	08:19
		Week 6	13-JUN-2001	07:10	13-JUN-2001	07:09
025	F-S	Week 1	10-MAY-2001	11:02	10-MAY-2001	11:04
		Week 2			20-MAY-2001	11:30
		Week 3	25-MAY-2001	11:44	25-MAY-2001	11:43
		Week 6	17-JUN-2001	11:39	17-JUN-2001	11:38
026	F-S	Week 1	11-MAY-2001	11:11	11-MAY-2001	11:11
		Week 2			14-MAY-2001	10:28
		Week 3	24-MAY-2001	10:55	24-MAY-2001	11:10
		Week 6	16-JUN-2001	11:17	16-JUN-2001	11:19
027	F-S	Week 1	11-MAY-2001	08:40	11-MAY-2001	08:42
		Week 2			16-MAY-2001	10:37
		Week 3	21-MAY-2001	09:12	21-MAY-2001	09:10
		Week 6	13-JUN-2001	11:05	13-JUN-2001	11:03
028	F-S	Week 1	11-MAY-2001	09:11	11-MAY-2001	09:12
		Week 2			17-MAY-2001	09:11
		Week 3	24-MAY-2001	09:09	24-MAY-2001	09:08
		Week 6	12-JUN-2001	09:11	12-JUN-2001	09:12
029	F-S	Week 1	11-MAY-2001	07:21	11-MAY-2001	07:26
		Week 2			16-MAY-2001	09:08
		Week 3	21-MAY-2001	09:56	21-MAY-2001	10:00
		Week 6	15-JUN-2001	10:00	15-JUN-2001	10:05

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-33
Exhalate Collection Times by Subject
(Page 5 of 20)

Subject Number	Subject Classification ^a	Timepoint	Acetonitrile		Carbon Monoxide	
			Date	Time	Date	Time
030	F-S	Week 1	10-MAY-2001	10:44	10-MAY-2001	10:45
		Week 2			14-MAY-2001	06:52
		Week 3	21-MAY-2001	07:12	21-MAY-2001	07:09
		Week 6	12-JUN-2001	06:30	12-JUN-2001	06:35
031	F-S	Week 1	10-MAY-2001	11:17	10-MAY-2001	11:18
		Week 2			15-MAY-2001	07:43
		Week 3	23-MAY-2001	08:40	23-MAY-2001	08:41
		Week 6	15-JUN-2001	10:00	15-JUN-2001	10:02
032	F-S	Week 1	11-MAY-2001	14:42	11-MAY-2001	14:45
		Week 2			20-MAY-2001	09:56
		Week 3	25-MAY-2001	08:54	25-MAY-2001	08:53
		Week 6	18-JUN-2001	06:07	18-JUN-2001	06:05
033	F-S	Week 1	11-MAY-2001	10:18	11-MAY-2001	10:21
		Week 2			15-MAY-2001	08:46
		Week 3	22-MAY-2001	07:55	22-MAY-2001	07:53
		Week 6	18-JUN-2001	08:11	18-JUN-2001	08:09
034	F-S	Week 1	11-MAY-2001	15:06	11-MAY-2001	15:07
		Week 2			20-MAY-2001	09:17
		Week 3	30-MAY-2001	08:30	30-MAY-2001	08:29
		Week 6	18-JUN-2001	12:16	18-JUN-2001	12:15
035	F-S	Week 1	10-MAY-2001	05:12	10-MAY-2001	05:13
		Week 2			16-MAY-2001	05:41
		Week 3	22-MAY-2001	06:18	22-MAY-2001	06:14
		Week 6	13-JUN-2001	05:52	13-JUN-2001	05:53
036	M-S	Week 1	09-MAY-2001	06:46	09-MAY-2001	06:48
		Week 2			15-MAY-2001	07:12
		Week 3	22-MAY-2001	06:40	22-MAY-2001	06:38
		Week 6	11-JUN-2001	06:33	11-JUN-2001	06:39

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-33
Exhale Collection Times by Subject
(Page 6 of 20)

Subject Number	Subject Classification ^a	Timepoint	Acetonitrile		Carbon Monoxide	
			Date	Time	Date	Time
037	M-S	Week 1	10-MAY-2001	10:06	10-MAY-2001	10:05
		Week 2			16-MAY-2001	06:22
		Week 3	22-MAY-2001	09:39	22-MAY-2001	09:39
		Week 6	13-JUN-2001	11:20	13-JUN-2001	11:18
038	M-S	Week 1	09-MAY-2001	09:04	09-MAY-2001	09:05
		Week 2			14-MAY-2001	08:55
		Week 3	21-MAY-2001	08:57	21-MAY-2001	08:59
		Week 6	11-JUN-2001	08:55	11-JUN-2001	08:59
039	M-S	Week 1	09-MAY-2001	06:41	09-MAY-2001	06:44
		Week 2			14-MAY-2001	06:30
		Week 3	21-MAY-2001	06:48	21-MAY-2001	06:45
		Week 6	11-JUN-2001	06:17	11-JUN-2001	06:17
040	M-S	Week 1	16-MAY-2001	09:34	16-MAY-2001	09:35
		Week 2			20-MAY-2001	08:19
		Week 3	24-MAY-2001	13:06	24-MAY-2001	13:10
		Week 6	17-JUN-2001	08:24	17-JUN-2001	08:24
041	M-S	Week 1	11-MAY-2001	14:38	11-MAY-2001	14:39
		Week 2			14-MAY-2001	09:44
		Week 3	21-MAY-2001	14:36	21-MAY-2001	14:35
		Week 6	13-JUN-2001	09:20	13-JUN-2001	09:09
042	M-S	Week 1	10-MAY-2001	11:41	10-MAY-2001	11:42
		Week 2			14-MAY-2001	13:01
		Week 3	24-MAY-2001	11:59	24-MAY-2001	11:57
		Week 6	11-JUN-2001	11:48	11-JUN-2001	11:49
043	M-S	Week 1	09-MAY-2001	09:36	09-MAY-2001	09:37
		Week 2			14-MAY-2001	09:48
		Week 3	23-MAY-2001	09:23	23-MAY-2001	09:26
		Week 6	11-JUN-2001	09:23	11-JUN-2001	09:24

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-33
Exhalate Collection Times by Subject
(Page 7 of 20)

Subject Number	Subject Classification ^a	Timepoint	Acetonitrile		Carbon Monoxide	
			Date	Time	Date	Time
044	M-S	Week 1	09-MAY-2001	12:25	09-MAY-2001	12:26
		Week 2			17-MAY-2001	12:23
		Week 3	23-MAY-2001	12:19	23-MAY-2001	12:15
		Week 6	14-JUN-2001	12:24	14-JUN-2001	12:23
045	M-S	Week 1	10-MAY-2001	14:48	10-MAY-2001	14:49
		Week 2			17-MAY-2001	12:20
		Week 3	24-MAY-2001	12:37	24-MAY-2001	12:35
		Week 6	11-JUN-2001	14:54	11-JUN-2001	14:55
046	M-S	Week 1	11-MAY-2001	09:20	11-MAY-2001	09:21
		Week 2			14-MAY-2001	09:27
		Week 3	21-MAY-2001	09:08	21-MAY-2001	09:10
		Week 6	12-JUN-2001	09:32	12-JUN-2001	09:33
047	M-S	Week 1	10-MAY-2001	14:44	10-MAY-2001	14:46
		Week 2			16-MAY-2001	10:07
		Week 3	23-MAY-2001	10:08	23-MAY-2001	10:09
		Week 6	13-JUN-2001	10:09	13-JUN-2001	10:08
048	M-S	Week 1	10-MAY-2001	09:11	10-MAY-2001	09:15
		Week 2			16-MAY-2001	09:12
		Week 3	21-MAY-2001	13:18	21-MAY-2001	13:17
		Week 6	12-JUN-2001	09:24	12-JUN-2001	09:23
049	M-S	Week 1	11-MAY-2001	06:33	11-MAY-2001	06:34
		Week 2			15-MAY-2001	08:33
		Week 3	23-MAY-2001	08:30	23-MAY-2001	08:32
		Week 6	11-JUN-2001	08:50	11-JUN-2001	08:51
050	M-S	Week 1	11-MAY-2001	07:24	11-MAY-2001	07:22
		Week 2			14-MAY-2001	08:19
		Week 3	23-MAY-2001	07:02	23-MAY-2001	06:58
		Week 6	18-JUN-2001	06:39	18-JUN-2001	06:37

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-33
 Exhale Collection Times by Subject
 (Page 8 of 20)

Subject Number	Subject Classification ^a	Timepoint	Acetonitrile		Carbon Monoxide	
			Date	Time	Date	Time
052	M-S	Week 1	11-MAY-2001	10:00	11-MAY-2001	10:02
		Week 2			18-MAY-2001	10:10
		Week 3	24-MAY-2001	12:07	24-MAY-2001	12:07
		Week 6	12-JUN-2001	12:03	12-JUN-2001	12:01
054	M-S	Week 1	10-MAY-2001	10:22	10-MAY-2001	10:20
		Week 2			16-MAY-2001	05:45
		Week 3	23-MAY-2001	11:17	23-MAY-2001	11:15
		Week 6	13-JUN-2001	11:44	13-JUN-2001	11:42
055	M-S	Week 1	10-MAY-2001	09:14	10-MAY-2001	09:10
		Week 2			15-MAY-2001	06:56
		Week 3	23-MAY-2001	07:01	23-MAY-2001	07:03
		Week 6	13-JUN-2001	06:51	13-JUN-2001	06:50
056	M-S	Week 1	11-MAY-2001	10:31	11-MAY-2001	10:34
		Week 2			20-MAY-2001	06:25
		Week 3	25-MAY-2001	06:43	25-MAY-2001	06:42
		Week 6	16-JUN-2001	08:15	16-JUN-2001	08:14
057	M-S	Week 1	10-MAY-2001	07:58	10-MAY-2001	07:59
		Week 2			15-MAY-2001	13:56
		Week 3	21-MAY-2001	13:58	21-MAY-2001	13:57
		Week 6	17-JUN-2001	12:04	17-JUN-2001	12:02
058	M-S	Week 1	11-MAY-2001	10:10	11-MAY-2001	10:11
		Week 2			20-MAY-2001	12:22
		Week 3	25-MAY-2001	10:16	25-MAY-2001	10:14
		Week 6	18-JUN-2001	09:51	18-JUN-2001	09:49
059	M-S	Week 1	10-MAY-2001	12:44	10-MAY-2001	12:42
		Week 2			16-MAY-2001	07:17
		Week 3	22-MAY-2001	08:36	22-MAY-2001	08:35
		Week 6	16-JUN-2001	08:33	16-JUN-2001	08:31

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-33
Exhale Collection Times by Subject
(Page 9 of 20)

Subject Number	Subject Classification ^a	Timepoint	Acetonitrile		Carbon Monoxide	
			Date	Time	Date	Time
060	M-S	Week 1	11-MAY-2001	12:17	11-MAY-2001	12:18
		Week 2			18-MAY-2001	10:41
		Week 3	25-MAY-2001	11:52	25-MAY-2001	11:52
		Week 6	14-JUN-2001	08:40	14-JUN-2001	08:42
061	M-S	Week 1	11-MAY-2001	15:11	11-MAY-2001	15:12
		Week 2			17-MAY-2001	08:06
		Week 3	23-MAY-2001	10:06	23-MAY-2001	10:05
		Week 6	14-JUN-2001	10:26	14-JUN-2001	10:24
062	M-S	Week 1	11-MAY-2001	11:41	11-MAY-2001	11:42
		Week 2			16-MAY-2001	11:58
		Week 3	24-MAY-2001	11:39	24-MAY-2001	11:38
		Week 6	14-JUN-2001	12:27	14-JUN-2001	12:30
063	M-S	Week 1	11-MAY-2001	08:21	11-MAY-2001	08:22
		Week 2			20-MAY-2001	10:36
		Week 3	25-MAY-2001	07:11	25-MAY-2001	07:11
		Week 6	15-JUN-2001	07:10	15-JUN-2001	07:08
065	M-S	Week 1	11-MAY-2001	12:50	11-MAY-2001	12:47
		Week 2			17-MAY-2001	08:39
		Week 3	22-MAY-2001	11:45	22-MAY-2001	11:43
		Week 6	16-JUN-2001	10:02	16-JUN-2001	10:18
067	M-S	Week 1	11-MAY-2001	11:44	11-MAY-2001	11:46
		Week 2			17-MAY-2001	07:35
		Week 3	24-MAY-2001	09:55	24-MAY-2001	09:54
		Week 6	15-JUN-2001	10:44	15-JUN-2001	10:42
068	M-S	Week 1	11-MAY-2001	11:23	11-MAY-2001	11:24
		Week 2			20-MAY-2001	11:00
		Week 3	25-MAY-2001	10:09	25-MAY-2001	10:08
		Week 6	17-JUN-2001	08:51	17-JUN-2001	08:50

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-33
Exhale Collection Times by Subject
(Page 10 of 20)

Subject Number	Subject Classification ^a	Timepoint	Acetonitrile		Carbon Monoxide	
			Date	Time	Date	Time
069	M-S	Week 1	15-MAY-2001	10:20	15-MAY-2001	10:14
		Week 2			22-MAY-2001	13:20
		Week 3	04-JUN-2001	11:26	04-JUN-2001	11:23
		Week 6	13-JUN-2001	05:51	13-JUN-2001	05:46
071	F-NS	Week 1	11-MAY-2001	10:50	11-MAY-2001	10:51
		Week 2			18-MAY-2001	08:49
		Week 3	22-MAY-2001	07:08	22-MAY-2001	07:05
		Week 6	12-JUN-2001	08:40	12-JUN-2001	08:40
072	F-NS	Week 1	09-MAY-2001	12:51	09-MAY-2001	12:53
		Week 2			14-MAY-2001	07:04
		Week 3	22-MAY-2001	08:19	22-MAY-2001	08:17
		Week 6	12-JUN-2001	07:07	12-JUN-2001	07:07
073	F-NS	Week 1	09-MAY-2001	07:21	09-MAY-2001	07:19
		Week 2			18-MAY-2001	10:22
		Week 3	22-MAY-2001	10:13	22-MAY-2001	10:11
		Week 6	13-JUN-2001	06:05	13-JUN-2001	06:05
074	F-NS	Week 1	09-MAY-2001	08:08	09-MAY-2001	08:09
		Week 2			14-MAY-2001	09:05
		Week 3	22-MAY-2001	11:06	22-MAY-2001	11:05
		Week 6	11-JUN-2001	07:15	11-JUN-2001	07:15
075	F-NS	Week 1	09-MAY-2001	07:35	09-MAY-2001	07:36
		Week 2			14-MAY-2001	14:03
		Week 3	23-MAY-2001	08:26	23-MAY-2001	08:25
		Week 6	14-JUN-2001	07:58	14-JUN-2001	07:58
076	F-NS	Week 1	11-MAY-2001	16:06	11-MAY-2001	16:14
		Week 2			20-MAY-2001	12:17
		Week 3	25-MAY-2001	12:04	25-MAY-2001	12:02
		Week 6	11-JUN-2001	14:53	11-JUN-2001	14:52

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-33
Exhale Collection Times by Subject
(Page 11 of 20)

Subject Number	Subject Classification ^a	Timepoint	Acetonitrile		Carbon Monoxide	
			Date	Time	Date	Time
077	F-NS	Week 1	09-MAY-2001	08:46	09-MAY-2001	08:49
		Week 2			14-MAY-2001	08:28
		Week 3	21-MAY-2001	08:34	21-MAY-2001	08:35
		Week 6	11-JUN-2001	08:04	11-JUN-2001	08:04
078	F-NS	Week 1	10-MAY-2001	12:51	10-MAY-2001	12:52
		Week 2			14-MAY-2001	13:59
		Week 3	21-MAY-2001	13:01	21-MAY-2001	12:59
		Week 6	13-JUN-2001	11:10	13-JUN-2001	11:09
079	F-NS	Week 1	09-MAY-2001	12:31	09-MAY-2001	12:34
		Week 2			14-MAY-2001	11:46
		Week 3	21-MAY-2001	11:55	21-MAY-2001	11:55
		Week 6	11-JUN-2001	12:04	11-JUN-2001	12:03
080	F-NS	Week 1	09-MAY-2001	06:33	09-MAY-2001	06:35
		Week 2			15-MAY-2001	07:07
		Week 3	21-MAY-2001	07:04	21-MAY-2001	07:02
		Week 6	11-JUN-2001	06:13	11-JUN-2001	06:14
081	F-NS	Week 1	09-MAY-2001	13:34	09-MAY-2001	13:31
		Week 2			14-MAY-2001	13:19
		Week 3	22-MAY-2001	13:14	22-MAY-2001	13:13
		Week 6	11-JUN-2001	13:26	11-JUN-2001	13:25
082	F-NS	Week 1	09-MAY-2001	05:29	09-MAY-2001	05:31
		Week 2			20-MAY-2001	11:16
		Week 3	25-MAY-2001	06:10	25-MAY-2001	06:09
		Week 6	18-JUN-2001	06:32	18-JUN-2001	06:31
083	F-NS	Week 1	10-MAY-2001	06:48	10-MAY-2001	06:49
		Week 2			15-MAY-2001	06:52
		Week 3	25-MAY-2001	09:34	25-MAY-2001	09:33
		Week 6	12-JUN-2001	07:15	12-JUN-2001	07:13

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-33
Exhale Collection Times by Subject
(Page 12 of 20)

Subject Number	Subject Classification ^a	Timepoint	Acetonitrile		Carbon Monoxide	
			Date	Time	Date	Time
084	F-NS	Week 1	09-MAY-2001	10:05	09-MAY-2001	10:06
		Week 2			14-MAY-2001	09:57
		Week 3	23-MAY-2001	09:53	23-MAY-2001	09:52
		Week 6	13-JUN-2001	10:05	13-JUN-2001	10:02
085	F-NS	Week 1	10-MAY-2001	10:17	10-MAY-2001	10:15
		Week 2			16-MAY-2001	10:25
		Week 3	23-MAY-2001	11:08	23-MAY-2001	11:08
		Week 6	11-JUN-2001	11:40	11-JUN-2001	11:40
086	F-NS	Week 1	10-MAY-2001	12:19	10-MAY-2001	12:19
		Week 2			15-MAY-2001	07:16
		Week 3	25-MAY-2001	11:06	25-MAY-2001	11:05
		Week 6	12-JUN-2001	06:27	12-JUN-2001	06:31
087	F-NS	Week 1	10-MAY-2001	09:59	10-MAY-2001	09:58
		Week 2			15-MAY-2001	07:54
		Week 3	22-MAY-2001	09:48	22-MAY-2001	09:46
		Week 6	11-JUN-2001	08:40	11-JUN-2001	08:41
088	F-NS	Week 1	09-MAY-2001	07:06	09-MAY-2001	07:07
		Week 2			14-MAY-2001	08:05
		Week 3	23-MAY-2001	07:08	23-MAY-2001	07:06
		Week 6	11-JUN-2001	07:03	11-JUN-2001	07:02
089	F-NS	Week 1	10-MAY-2001	08:40	10-MAY-2001	08:41
		Week 2			16-MAY-2001	07:44
		Week 3	22-MAY-2001	08:30	22-MAY-2001	08:29
		Week 6	11-JUN-2001	14:25	11-JUN-2001	14:25
090	F-NS	Week 1	10-MAY-2001	08:17	10-MAY-2001	08:17
		Week 2			14-MAY-2001	08:42
		Week 3	24-MAY-2001	08:20	24-MAY-2001	08:19
		Week 6	12-JUN-2001	08:51	12-JUN-2001	08:52

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-33
Exhalate Collection Times by Subject
(Page 13 of 20)

Subject Number	Subject Classification ^a	Timepoint	Acetonitrile		Carbon Monoxide	
			Date	Time	Date	Time
091	F-NS	Week 1	10-MAY-2001	08:28	10-MAY-2001	08:26
		Week 2			15-MAY-2001	08:38
		Week 3	22-MAY-2001	08:40	22-MAY-2001	08:43
		Week 6	12-JUN-2001	08:45	12-JUN-2001	08:46
092	F-NS	Week 1	10-MAY-2001	09:06	10-MAY-2001	09:04
		Week 2			15-MAY-2001	09:00
		Week 3	21-MAY-2001	08:46	21-MAY-2001	08:47
		Week 6	14-JUN-2001	07:31	14-JUN-2001	07:32
093	F-NS	Week 1	10-MAY-2001	10:38	10-MAY-2001	10:39
		Week 2			16-MAY-2001	10:40
		Week 3	22-MAY-2001	10:51	22-MAY-2001	10:49
		Week 6	13-JUN-2001	10:44	13-JUN-2001	10:41
094	F-NS	Week 1	10-MAY-2001	06:59	10-MAY-2001	07:00
		Week 2			16-MAY-2001	09:40
		Week 3	21-MAY-2001	10:15	21-MAY-2001	10:16
		Week 6	13-JUN-2001	09:13	13-JUN-2001	09:18
095	F-NS	Week 1	09-MAY-2001	13:17	09-MAY-2001	13:19
		Week 2			15-MAY-2001	11:26
		Week 3	23-MAY-2001	14:37	23-MAY-2001	14:36
		Week 6	12-JUN-2001	11:26	12-JUN-2001	11:28
096	F-NS	Week 1	11-MAY-2001	13:03	11-MAY-2001	13:04
		Week 2			15-MAY-2001	13:10
		Week 3	21-MAY-2001	13:13	21-MAY-2001	13:13
		Week 6	17-JUN-2001	09:23	17-JUN-2001	09:22
097	F-NS	Week 1	11-MAY-2001	09:39	11-MAY-2001	09:40
		Week 2			20-MAY-2001	09:12
		Week 3	25-MAY-2001	09:24	25-MAY-2001	09:26
		Week 6	16-JUN-2001	09:09	16-JUN-2001	09:07

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

*Listing 16.5-33
Exhalate Collection Times by Subject
(Page 14 of 20)

Subject Number	Subject Classification ^a	Timepoint	Acetonitrile		Carbon Monoxide	
			Date	Time	Date	Time
098	F-NS	Week 1	09-MAY-2001	15:33	09-MAY-2001	15:35
		Week 2			15-MAY-2001	15:04
		Week 3	24-MAY-2001	15:11	24-MAY-2001	15:10
		Week 6	11-JUN-2001	14:58	11-JUN-2001	14:58
099	F-NS	Week 1	09-MAY-2001	13:55	09-MAY-2001	13:56
		Week 2			14-MAY-2001	07:11
		Week 3	22-MAY-2001	11:36	22-MAY-2001	11:34
		Week 6	11 JUN 2001	10:01	11 JUN 2001	10:02
100	F-NS	Week 1	10-MAY-2001	06:25	10-MAY-2001	06:28
		Week 2			18-MAY-2001	06:23
		Week 3	23-MAY-2001	06:22	23-MAY-2001	06:24
		Week 6	14-JUN-2001	06:21	14-JUN-2001	06:19
101	F-NS	Week 1	11-MAY-2001	06:15	11-MAY-2001	06:17
		Week 2			14-MAY-2001	06:20
		Week 3	25-MAY-2001	06:38	25-MAY-2001	06:37
		Week 6	17-JUN-2001	09:42	17-JUN-2001	09:40
102	F-NS	Week 1	09-MAY-2001	14:14	09-MAY-2001	14:15
		Week 2			20-MAY-2001	11:40
		Week 3	25-MAY-2001	10:24	25-MAY-2001	10:23
		Week 6	12-JUN-2001	07:39	12-JUN-2001	07:39
103	F-NS	Week 1	10-MAY-2001	08:05	10-MAY-2001	08:03
		Week 2			20-MAY-2001	12:45
		Week 3	24-MAY-2001	08:54	24-MAY-2001	08:53
		Week 6	18 JUN 2001	09:07	18 JUN 2001	09:06
104	M-NS	Week 1	07-MAY-2001	09:27	07-MAY-2001	09:24
		Week 2			17-MAY-2001	07:40
		Week 3	22-MAY-2001	06:57	22-MAY-2001	06:55
		Week 6	11-JUN-2001	07:51	11-JUN-2001	07:51

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-33
Exhale Collection Times by Subject
(Page 15 of 20)

Subject Number	Subject Classification*	Timepoint	Acetonitrile		Carbon Monoxide	
			Date	Time	Date	Time
105	M-NS	Week 1	09-MAY-2001	15:12	09-MAY-2001	15:14
		Week 2			16-MAY-2001	09:01
		Week 3	23-MAY-2001	06:18	23-MAY-2001	06:19
		Week 6	14-JUN-2001	06:03	14-JUN-2001	06:01
106	M-NS	Week 1	11-MAY-2001	13:24	11-MAY-2001	13:25
		Week 2			18-MAY-2001	07:00
		Week 3	23-MAY-2001	08:02	23-MAY-2001	08:00
		Week 6	11-JUN-2001	07:35	11-JUN-2001	07:34
107	M-NS	Week 1	11-MAY-2001	06:36	11-MAY-2001	06:37
		Week 2			17-MAY-2001	07:09
		Week 3	23-MAY-2001	07:06	23-MAY-2001	07:10
		Week 6	16-JUN-2001	11:02	16-JUN-2001	11:03
108	M-NS	Week 1	09-MAY-2001	12:03	09-MAY-2001	12:04
		Week 2			14-MAY-2001	11:53
		Week 3	21-MAY-2001	12:08	21-MAY-2001	12:06
		Week 6	13-JUN-2001	12:04	13-JUN-2001	12:04
109	M-NS	Week 1	09-MAY-2001	08:50	09-MAY-2001	08:53
		Week 2			14-MAY-2001	08:38
		Week 3	21-MAY-2001	08:39	21-MAY-2001	08:41
		Week 6	11-JUN-2001	08:05	11-JUN-2001	08:07
110	M-NS	Week 1	10-MAY-2001	08:20	10-MAY-2001	08:21
		Week 2			18-MAY-2001	08:32
		Week 3	22-MAY-2001	08:10	22-MAY-2001	08:09
		Week 6	12-JUN-2001	08:13	12-JUN-2001	08:14
111	M-NS	Week 1	09-MAY-2001	06:35	09-MAY-2001	06:39
		Week 2			14-MAY-2001	06:38
		Week 3	21-MAY-2001	06:59	21-MAY-2001	06:56
		Week 6	11-JUN-2001	06:08	11-JUN-2001	06:10

* Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-33
Exhale Collection Times by Subject
(Page 16 of 20)

Subject Number	Subject Classification ^a	Timepoint	Acetonitrile		Carbon Monoxide	
			Date	Time	Date	Time
112	M-NS	Week 1	11-MAY-2001	07:13	11-MAY-2001	07:14
		Week 2			15-MAY-2001	07:37
		Week 3	21-MAY-2001	07:49	21-MAY-2001	07:49
		Week 6	11-JUN-2001	07:46	11-JUN-2001	07:47
113	M-NS	Week 1	11-MAY-2001	07:09	11-MAY-2001	07:10
		Week 2			15-MAY-2001	07:34
114	M-NS	Week 1	11-MAY-2001	11:35	11-MAY-2001	11:36
		Week 2			20-MAY-2001	07:18
		Week 3	24-MAY-2001	10:28	24-MAY-2001	10:26
		Week 6	14-JUN-2001	10:16	14-JUN-2001	10:14
115	M-NS	Week 1	09-MAY-2001	10:24	09-MAY-2001	10:25
		Week 2			18-MAY-2001	10:34
		Week 3	22-MAY-2001	10:42	22-MAY-2001	10:41
		Week 6	15-JUN-2001	09:36	15-JUN-2001	09:35
116	M-NS	Week 1	09-MAY-2001	06:52	09-MAY-2001	06:54
		Week 2			15-MAY-2001	13:51
		Week 3	21-MAY-2001	06:08	21-MAY-2001	06:09
		Week 6	08-JUN-2001	06:03	08-JUN-2001	06:14
117	M-NS	Week 1	09-MAY-2001	11:18	09-MAY-2001	11:19
		Week 2			16-MAY-2001	11:39
		Week 3	22-MAY-2001	13:54	22-MAY-2001	13:55
		Week 6	13-JUN-2001	06:38	13-JUN-2001	06:36
118	M-NS	Week 1	10 MAY 2001	13:02	10-MAY-2001	13:04
		Week 2			15-MAY-2001	13:28
		Week 3	24-MAY-2001	11:55	24-MAY-2001	11:53
		Week 6	12-JUN-2001	12:33	12-JUN-2001	12:29
119	M-NS	Week 1	09-MAY-2001	11:55	09-MAY-2001	11:55
		Week 2			14-MAY-2001	11:41
		Week 3	21-MAY-2001	11:51	21-MAY-2001	11:49
		Week 6	12-JUN-2001	11:49	12-JUN-2001	11:46

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-33
Exhale Collection Times by Subject
(Page 17 of 20)

Subject Number	Subject Classification ^a	Timepoint	Acetonitrile		Carbon Monoxide	
			Date	Time	Date	Time
120	M-NS	Week 1	09-MAY-2001	09:00	09-MAY-2001	09:01
		Week 2			14-MAY-2001	09:23
		Week 3	23-MAY-2001	09:22	23-MAY-2001	09:23
		Week 6	11-JUN-2001	08:57	11-JUN-2001	09:03
121	M-NS	Week 1	09-MAY-2001	11:13	09-MAY-2001	11:14
		Week 2			14-MAY-2001	11:00
		Week 3	22-MAY-2001	10:58	22-MAY-2001	10:57
		Week 6	11-JUN-2001	10:54	11-JUN-2001	10:52
122	M-NS	Week 1	10-MAY-2001	13:25	10-MAY-2001	13:26
		Week 2			14-MAY-2001	11:30
		Week 3	21-MAY-2001	11:39	21-MAY-2001	11:37
		Week 6	13-JUN-2001	11:33	13-JUN-2001	11:31
123	M-NS	Week 1	11-MAY-2001	05:50	11-MAY-2001	05:48
		Week 2			15-MAY-2001	05:53
		Week 3	23-MAY-2001	08:57	23-MAY-2001	08:56
		Week 6	12-JUN-2001	08:55	12-JUN-2001	08:57
124	M-NS	Week 1	10-MAY-2001	11:35	10-MAY-2001	11:37
		Week 2			15-MAY-2001	12:06
		Week 3	22-MAY-2001	12:15	22-MAY-2001	12:14
		Week 6	13-JUN-2001	12:20	13-JUN-2001	12:19
125	M-NS	Week 1	09-MAY-2001	13:42	09-MAY-2001	13:41
		Week 2			16-MAY-2001	08:53
		Week 3	23-MAY-2001	15:08	23-MAY-2001	15:06
		Week 6	18-JUN-2001	09:25	18-JUN-2001	09:26
126	M-NS	Week 1	09-MAY-2001	13:26	09-MAY-2001	13:24
		Week 2			15-MAY-2001	11:32
		Week 3	23-MAY-2001	14:37	23-MAY-2001	14:40
		Week 6	12-JUN-2001	11:29	12-JUN-2001	11:33

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-33
Exhalate Collection Times by Subject
(Page 18 of 20)

Subject Number	Subject Classification ^a	Timepoint	Acetonitrile		Carbon Monoxide	
			Date	Time	Date	Time
127	M-NS	Week 1	11-MAY-2001	10:37	11-MAY-2001	10:39
		Week 2			14-MAY-2001	13:05
		Week 3	23-MAY-2001	09:13	23-MAY-2001	09:17
		Week 6	11-JUN-2001	12:56	11-JUN-2001	12:57
128	M-NS	Week 1	10-MAY-2001	13:18	10-MAY-2001	13:20
		Week 2			14-MAY-2001	12:31
		Week 3	21-MAY-2001	12:29	21-MAY-2001	12:27
		Week 6	13-JUN-2001	12:39	13-JUN-2001	12:37
129	M-NS	Week 1	10-MAY-2001	08:02	10-MAY-2001	08:06
		Week 2			14-MAY-2001	15:03
		Week 3	22-MAY-2001	14:57	22-MAY-2001	14:55
		Week 6	11-JUN-2001	11:00	11-JUN-2001	11:00
130	M-NS	Week 1	10-MAY-2001	11:45	10-MAY-2001	11:46
		Week 2			15-MAY-2001	11:44
		Week 3	23-MAY-2001	11:44	23-MAY-2001	11:47
		Week 6	13-JUN-2001	11:39	13-JUN-2001	11:39
131	M-NS	Week 1	10-MAY-2001	08:56	10-MAY-2001	08:55
		Week 2			14-MAY-2001	07:58
		Week 3	21-MAY-2001	07:38	21-MAY-2001	07:39
		Week 6	12-JUN-2001	07:46	12-JUN-2001	07:47
132	M-NS	Week 1	10-MAY-2001	07:28	10-MAY-2001	07:29
		Week 2			18-MAY-2001	08:16
		Week 3	24-MAY-2001	09:15	24-MAY-2001	09:15
		Week 6	15-JUN-2001	08:13	15-JUN-2001	08:11
133	M-NS	Week 1	10-MAY-2001	13:38	10-MAY-2001	13:39
		Week 2			16-MAY-2001	08:34
		Week 3	23-MAY-2001	10:35	23-MAY-2001	10:33
		Week 6	14-JUN-2001	08:30	14-JUN-2001	08:28

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-33
Exhalate Collection Times by Subject
(Page 19 of 20)

Subject Number	Subject Classification ^a	Timepoint	Acetonitrile		Carbon Monoxide	
			Date	Time	Date	Time
134	M-NS	Week 1	16-MAY-2001	11:16	16-MAY-2001	11:09
		Week 2			24-MAY-2001	13:20
		Week 3	30-MAY-2001	11:17	30-MAY-2001	11:16
		Week 6	18-JUN-2001	11:02	18-JUN-2001	11:02
135	M-NS	Week 1	11-MAY-2001	08:34	11-MAY-2001	08:34
		Week 2			17-MAY-2001	08:35
		Week 3	23-MAY-2001	10:13	23-MAY-2001	10:14
		Week 6	12-JUN-2001	13:59	12-JUN-2001	13:57
500	F-NS	Week 1	09-MAY-2001	14:17	09-MAY-2001	14:19
		Week 2			14-MAY-2001	13:16
		Week 3	22-MAY-2001	10:35	22-MAY-2001	10:33
		Week 6	11-JUN-2001	12:45	11-JUN-2001	12:46
501	F-NS	Week 1	11-MAY-2001	08:47	11-MAY-2001	08:51
		Week 2			15-MAY-2001	09:36
		Week 3	23-MAY-2001	09:13	23-MAY-2001	09:13
		Week 6	14-JUN-2001	08:18	14-JUN-2001	08:17
502	F-S	Week 1	14-MAY-2001	09:12	14-MAY-2001	09:14
		Week 2			20-MAY-2001	10:13
		Week 3	24-MAY-2001	08:24	24-MAY-2001	08:26
		Week 6	14-JUN-2001	08:44	14-JUN-2001	08:45
503	F-S	Week 1	10-MAY-2001	11:08	10-MAY-2001	11:09
		Week 2			16-MAY-2001	11:35
		Week 3	21-MAY-2001	11:14	21-MAY-2001	11:13
		Week 6	11-JUN-2001	10:22	11-JUN-2001	10:28
504	F-S	Week 1	11-MAY-2001	12:38	11-MAY-2001	12:39
		Week 2			15-MAY-2001	12:28
		Week 3	24-MAY-2001	12:27	24-MAY-2001	12:25
		Week 6	12-JUN-2001	12:11	12-JUN-2001	12:09

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-33
Exhalate Collection Times by Subject
(Page 20 of 20)

Subject Number	Subject Classification ^a	Timepoint	Acetonitrile		Carbon Monoxide	
			Date	Time	Date	Time
505	F-NS	Week 1	11-MAY-2001	05:34	11-MAY-2001	05:36
		Week 2			18-MAY-2001	06:26
		Week 3	25-MAY-2001	06:46	25-MAY-2001	06:47
		Week 6	12-JUN-2001	06:16	12-JUN-2001	06:22
506	F-S	Week 1	11-MAY-2001	12:57	11-MAY-2001	12:59
		Week 2			17-MAY-2001	13:07
		Week 3	24-MAY-2001	13:06	24-MAY-2001	13:04
		Week 6	11-JUN-2001	12:53	11-JUN-2001	12:54

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS= Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-34
Spontaneous Sputum Collection by Subject
(Page 1 of 23)

Subject Number	Subject Classification ^a	Timepoint	Date	Sample Collected?	Sample Weight (mg)	Collected On/Off Site
001	F-S	Enrollment		No		
		Week 1		No		
		Week 6		No		
002	F-S	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6	11 JUN-2001	Yes	780.0	Off Site
003	F-S	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
004	F-S	Enrollment		No		
		Week 1		No		
		Week 3		No		
		Week 3		No		
		Week 6	11-JUN-2001	Yes	430.0	Off Site
005	F-S	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
006	F-S	Enrollment		No		
		Week 1		No		
		Week 2	15-MAY-2001	Yes	2270.0	Off Site
		Week 3		No		
		Week 6	12-JUN-2001	Yes	1620.0	Off Site

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630275

Draft 1: 24 July 2002

Page 14928 of 15132

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-34
Spontaneous Sputum Collection by Subject
(Page 2 of 23)

Subject Number	Subject Classification ^a	Timepoint	Date	Sample Collected?	Sample Weight (mg)	Collected On/Off Site
007	F-S	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
008	F-S	Enrollment	01-MAY-2001	Yes	310.0	On Site
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6	15-JUN-2001	Yes	230.0	On Site
009	F-S	Enrollment	01-MAY-2001	Yes	290.0	On Site
		Week 1		No		
		Week 2	14-MAY-2001	Yes	710.0	On Site
		Week 3		No		
		Week 6	11-JUN-2001	Yes	530.0	Off Site
010	F-S	Enrollment		No		
		Week 1		No		
		Week 2		No		
011	F-S	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
012	F-S	Enrollment		No		
		Week 1		No		
		Week 2	16-MAY-2001	Yes	2170.0	Off Site
		Week 3		No		
		Week 6	16-JUN-2001	Yes	1210.0	Off Site

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630276

Draft 1: 24 July 2002

Page 14929 of 15132

Listing 16.5-34
Spontaneous Sputum Collection by Subject
(Page 3 of 23)

Subject Number	Subject Classification ^a	Timepoint	Date	Sample Collected?	Sample Weight (mg)	Collected On/Off Site
013	F-S	Enrollment		No		
		Week 1		No		
		Week 2	14-MAY-2001	Yes	1000.0	On Site
		Week 3		No		
		Week 6		No		
014	F-S	Enrollment	01-MAY-2001	Yes	480.0	On Site
		Week 1	09-MAY-2001	Yes	200.0	Off Site
		Week 2		No		
		Week 3		No		
		Week 6	11-JUN-2001	Yes	750.0	Off Site
015	F-S	Enrollment	01-MAY-2001	Yes	790.0	On Site
		Week 1		No		
		Week 2	14-MAY-2001	Yes	2020.0	On Site
		Week 3		No		
		Week 6		Unknown		
016	F-S	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
017	F-S	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
018	F-S	Enrollment		No		
		Week 1	09-MAY-2001	Yes	790.0	On Site
		Week 2	15-MAY-2001	Yes	390.0	Off Site
		Week 3	22-MAY-2001	Yes	520.0	On Site
		Week 6	12-JUN-2001	Yes	660.0	Off Site

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-34
Spontaneous Sputum Collection by Subject
(Page 4 of 23)

Subject Number	Subject Classification ^a	Timepoint	Date	Sample Collected?	Sample Weight (mg)	Collected On/Off Site
019	F-S	Enrollment		No		
		Week 1		No		
		Week 2	17-MAY-2001	Yes	1020.0	Off Site
		Week 3	22-MAY-2001	Yes	630.0	On Site
		Week 6		Unknown		
020	F-S	Enrollment	02-MAY-2001	Yes	560.0	On Site
		Week 1	09-MAY-2001	Yes	1120.0	On Site
		Week 2	16-MAY-2001	Yes	1070.0	Off Site
		Week 3	23-MAY-2001	Yes	1200.0	On Site
		Week 6	13-JUN-2001	Yes	1150.0	Off Site
021	F-S	Enrollment		No		
		Week 1		No		
		Week 2	14-MAY-2001	Yes	690.0	On Site
		Week 3		No		
		Week 6	17-JUN-2001	Yes	840.0	Off Site
022	F-S	Enrollment		No		
		Week 1	10-MAY-2001	Yes	360.0	Off Site
		Week 2	17-MAY-2001	Yes	950.0	Off Site
		Week 3		No		
		Week 6		No		
023	F-S	Enrollment		No		
		Week 1	10-MAY-2001	Yes	240.0	Off Site
		Week 2		No		
		Week 3		No		
		Week 6		No		
024	F-S	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-34
Spontaneous Sputum Collection by Subject
(Page 5 of 23)

Subject Number	Subject Classification ^a	Timepoint	Date	Sample Collected?	Sample Weight (mg)	Collected On/Off Site
025	F-S	Enrollment	25-MAY-2001	No	200.0	On Site
		Week 1		No		
		Week 2		No		
		Week 3		Yes		
		Week 6		No		
026	F-S	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
027	F-S	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
028	F-S	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
029	F-S	Enrollment	11-MAY-2001	No	2420.0	Off Site
		Week 1		Yes		
		Week 2		Yes		
		Week 3		Yes		
		Week 6		Yes		
030	F-S	Enrollment	10-MAY-2001	No	160.0	On Site
		Week 1		Yes		
		Week 2		No		
		Week 3		Yes		
		Week 6		No		

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-34
Spontaneous Sputum Collection by Subject
(Page 6 of 23)

Subject Number	Subject Classification*	Timepoint	Date	Sample Collected?	Sample Weight (mg)	Collected On/Off Site
031	F-S	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
032	F-S	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
033	F-S	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
034	F-S	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3	30-MAY-2001	Yes	270.0	Off Site
		Week 6		No		
035	F-S	Enrollment		No		
		Week 1	10-MAY-2001	Yes	370.0	Off Site
		Week 2		No		
		Week 3		No		
		Week 6		No		
036	M-S	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		

* Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630280

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-34
Spontaneous Sputum Collection by Subject
(Page 7 of 23)

Subject Number	Subject Classification ^a	Timepoint	Date	Sample Collected?	Sample Weight (mg)	Collected On/Off Site
037	M-S	Enrollment	01-MAY-2001	Yes	206.0	On Site
		Week 1	10-MAY-2001	Yes	1320.0	On Site
		Week 2	16-MAY-2001	Yes	930.0	On Site
		Week 3		No		
		Week 6		No		
038	M-S	Enrollment	01-MAY-2001	Yes	1220.0	On Site
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
039	M-S	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3	21-MAY-2001	Yes	1330.0	Off Site
		Week 6		No		
040	M-S	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
041	M-S	Enrollment		No		
		Week 1	11-MAY-2001	Yes	1730.0	On Site
		Week 2	14-MAY-2001	Yes	1000.0	On Site
		Week 3		No		
		Week 6	13-JUN-2001	Yes	1630.0	Off Site
042	M-S	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630281

Listing 16.5-34
Spontaneous Sputum Collection by Subject
(Page 8 of 23)

Subject Number	Subject Classification ^a	Timepoint	Date	Sample Collected?	Sample Weight (mg)	Collected On/Off Site
043	M-S	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6	11-JUN-2001	Yes	1140.0	Off Site
044	M-S	Enrollment		No		
		Week 1	09-MAY-2001	Yes	400.0	On Site
		Week 2	17-MAY-2001	Yes	380.0	Off Site
		Week 3		No		
		Week 6		No		
045	M-S	Enrollment	02-MAY-2001	Yes	770.0	On Site
		Week 1	10-MAY-2001	Yes	1450.0	Off Site
		Week 2	17-MAY-2001	Yes	660.0	Off Site
		Week 3		No		
		Week 6		No		
046	M-S	Enrollment	02-MAY-2001	Yes	560.0	On Site
		Week 1	11-MAY-2001	Yes	600.0	Off Site
		Week 2	14-MAY-2001	Yes	520.0	On Site
		Week 3		No		
		Week 6	12-JUN-2001	Yes	440.0	On Site
047	M-S	Enrollment	02-MAY-2001	Yes	460.0	On Site
		Week 1	10-MAY-2001	Yes	1650.0	Off Site
		Week 2	16-MAY-2001	Yes	1210.0	Off Site
		Week 3	23-MAY-2001	Yes	1500.0	On Site
		Week 6	13-JUN-2001	Yes	1890.0	Off Site
048	M-S	Enrollment		No		
		Week 1	10-MAY-2001	Yes	1370.0	Off Site
		Week 2	16-MAY-2001	Yes	800.0	Off Site
		Week 3		No		
		Week 6		No		

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-34
Spontaneous Sputum Collection by Subject
(Page 9 of 23)

Subject Number	Subject Classification ^a	Timepoint	Date	Sample Collected?	Sample Weight (mg)	Collected On/Off Site
049	M-S	Enrollment		No		
		Week 1	11-MAY-2001	Yes	3190.0	Off Site
		Week 2	15-MAY-2001	Yes	2990.0	Off Site
		Week 3	23-MAY-2001	Yes	2460.0	Off Site
		Week 6		No		
050	M-S	Enrollment		No		
		Week 1	11-MAY-2001	Yes	370.0	Off Site
		Week 2		No		
		Week 3		No		
		Week 6		No		
051	M-S	Enrollment		No		
052	M-S	Enrollment		No		
		Week 1		No		
		Week 2	18-MAY-2001	Yes	1830.0	Off Site
		Week 3		No		
		Week 6	12-JUN-2001	Yes	670.0	Off Site
053	M-S	Enrollment	02-MAY-2001	Yes	1680.0	On Site
054	M-S	Enrollment		No		
		Week 1	10-MAY-2001	Yes	3320.0	Off Site
		Week 2	16-MAY-2001	Yes	3120.0	On Site
		Week 3		No		
		Week 6		No		
055	M-S	Enrollment	03-MAY-2001	Yes	710.0	On Site
		Week 1	10-MAY-2001	Yes	750.0	Off Site
		Week 2	15-MAY-2001	Yes	410.0	Off Site
		Week 3	23-MAY-2001	Yes	840.0	Off Site
		Week 6	13-JUN-2001	Yes	500.0	Off Site

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-34
Spontaneous Sputum Collection by Subject
(Page 10 of 23)

Subject Number	Subject Classification ^a	Timepoint	Date	Sample Collected?	Sample Weight (mg)	Collected On/Off Site
056	M-S	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
057	M-S	Enrollment	03-MAY-2001	Yes	1180.0	On Site
		Week 1	10-MAY-2001	Yes	670.0	On Site
		Week 2	15-MAY-2001	Yes	540.0	On Site
		Week 3	21-MAY-2001	Yes	580.0	On Site
		Week 6	17-JUN-2001	Yes	1300.0	Off Site
058	M-S	Enrollment	03-MAY-2001	Yes	630.0	On Site
		Week 1	11-MAY-2001	Yes	460.0	On Site
		Week 2	20-MAY-2001	Yes	1010.0	On Site
		Week 3		No		
		Week 6	18-JUN-2001	Yes	200.0	On Site
059	M-S	Enrollment		No		
		Week 1	10-MAY-2001	Yes ^b	990.0	Off Site
		Week 2	16-MAY-2001	Yes	910.0	Off Site
		Week 3		No		
		Week 6		No		
060	M-S	Enrollment		No		
		Week 1		No		
		Week 2	18-MAY-2001	Yes	1180.0	Off Site
		Week 3		No		
		Week 6		No		
061	M-S	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		Unknown		

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b A sputum sample sat ambient for an extended period and was discarded.

Listing 16.5-34
Spontaneous Sputum Collection by Subject
(Page 11 of 23)

Subject Number	Subject Classification ^a	Timepoint	Date	Sample Collected?	Sample Weight (mg)	Collected On/Off Site
062	M-S	Enrollment	03-MAY-2001	Yes	1640.0	On Site
		Week 1		No		
		Week 2	16-MAY-2001	Yes	100.0	Off Site
		Week 3	24-MAY-2001	Yes	1530.0	On Site
		Week 6		No		
063	M-S	Enrollment		No		
		Week 1		No		
		Week 2	22-MAY-2001	Yes	770.0	On Site
		Week 3		No		
		Week 6		No		
065	M-S	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
066	M-S	Enrollment		No		
067	M-S	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
068	M-S	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
069	M-S	Enrollment	10-MAY-2001	Yes	1500.0	Off Site
		Week 1	15-MAY-2001	Yes	1180.0	Off Site
		Week 2		No		
		Week 3		No		
		Week 6		No		

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-34
Spontaneous Sputum Collection by Subject
(Page 12 of 23)

Subject Number	Subject Classification ^a	Timepoint	Date	Sample Collected?	Sample Weight (mg)	Collected On/OFF Site
071	F-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
072	F-NS	Enrollment	01-MAY-2001	Yes	680.0	On Site
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
073	F-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
074	F-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
075	F-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
076	F-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630286

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.3-34
Spontaneous Sputum Collection by Subject
(Page 13 of 23)

Subject Number	Subject Classification ^a	Timepoint	Date	Sample Collected?	Sample Weight (mg)	Collected On/Off Site
077	F-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
078	F-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
079	F-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
080	F-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
081	F-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
082	F-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630287

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-34
Spontaneous Sputum Collection by Subject
(Page 14 of 23)

Subject Number	Subject Classification ^a	Timepoint	Date	Sample Collected?	Sample Weight (mg)	Collected On/Off Site
083	F-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
084	F-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6	13-JUN-2001	Yes	2210.0	On Site
085	F-NS	Enrollment		No		
		Week 1	10-MAY-2001	Yes	570.0	Off Site
		Week 2	16-MAY-2001	Yes	1490.0	Off Site
		Week 3		No		
		Week 6		No		
086	F-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
087	F-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
088	F-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630288

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-34
Spontaneous Sputum Collection by Subject
(Page 15 of 23)

Subject Number	Subject Classification ^a	Timepoint	Date	Sample Collected?	Sample Weight (mg)	Collected On/Off Site
089	F-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
090	F-NS	Enrollment	02-MAY-2001	Yes	310.0	On Site
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
091	F-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
092	F-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3	21-MAY-2001	Yes	1050.0	On Site
		Week 6		No		
093	F-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		Unknown		
094	F-NS	Enrollment		No		
		Week 1	10-MAY-2001	Yes	520.0	Off Site
		Week 2	16-MAY-2001	Yes	660.0	Off Site
		Week 3		No		
		Week 6	13-JUN-2001	Yes	370.0	Off Site

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630289

Listing 16.5-34
Spontaneous Sputum Collection by Subject
(Page 16 of 23)

Subject Number	Subject Classification ^a	Timepoint	Date	Sample Collected?	Sample Weight (mg)	Collected On/Off Site
095	F-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
096	F-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
097	F-NS	Enrollment		No		
		Week 1		No		
		Week 2	20-MAY-2001	Yes	1000.0	On Site
		Week 3		No		
		Week 6		No		
098	F-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
099	F-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
100	F-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-34
Spontaneous Sputum Collection by Subject
(Page 17 of 23)

Subject Number	Subject Classification ^a	Timepoint	Date	Sample Collected?	Sample Weight (mg)	Collected On/Off Site
101	F-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
102	F-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
103	F-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
104	M-NS	Enrollment		No		
		Week 1	07-MAY-2001	Yes	9999.0	On Site
		Week 2		No		
		Week 3		No		
		Week 6		No		
105	M-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
106	M-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-34
Spontaneous Sputum Collection by Subject
(Page 18 of 23)

Subject Number	Subject Classification ^a	Timepoint	Date	Sample Collected?	Sample Weight (mg)	Collected On/Off Site
107	M-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
108	M-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
109	M-NS	Enrollment	09-MAY-2001	No	280.0	On Site
		Week 1		Yes		
		Week 2		No		
		Week 3		No		
		Week 6		No		
110	M-NS	Enrollment		No		
		Week 1		No		
		Week 2		Unknown		
		Week 3		No		
		Week 6		No		
111	M-NS	Enrollment	14-MAY-2001	No	260.0	On Site
		Week 1		No		
		Week 2		Yes		
		Week 3		No		
		Week 6		No		
112	M-NS	Enrollment	01-MAY-2001	Yes	310.0	On Site
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-34
Spontaneous Sputum Collection by Subject
(Page 19 of 23)

Subject Number	Subject Classification ^a	Timepoint	Date	Sample Collected?	Sample Weight (mg)	Collected On/Off Site
113	M-NS	Enrollment	01-MAY-2001	Yes	810.0	On Site
		Week 1		No		
		Week 2		No		
114	M-NS	Enrollment	01-MAY-2001	Yes	1480.0	On Site
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
115	M-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
116	M-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
117	M-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6	13-JUN-2001	Yes	2230.0	Off Site
118	M-NS	Enrollment		No		
		Week 1		No		
		Week 2	15-MAY-2001	Yes	390.0	On Site
		Week 3		No		
		Week 6	12-JUN-2001	Yes	740.0	On Site

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630293

Draft 1: 24 July 2002

Page 14946 of 15132

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-34
Spontaneous Sputum Collection by Subject
(Page 20 of 23)

Subject Number	Subject Classification ^a	Timepoint	Date	Sample Collected?	Sample Weight (mg)	Collected On/Off Site
119	M-NS	Enrollment		Unknown		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
120	M-NS	Enrollment	02-MAY-2001	Yes	910.0	On Site
		Week 1		No		
		Week 2	14 MAY 2001	Yes	370.0	On Site
		Week 3		No		
		Week 6		No		
121	M-NS	Enrollment		No		
		Week 1		No		
		Week 2	14-MAY-2001	Yes	450.0	On Site
		Week 3		No		
		Week 6		No		
122	M-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
123	M-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
124	M-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630294

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-34
Spontaneous Sputum Collection by Subject
(Page 21 of 23)

Subject Number	Subject Classification ^a	Timepoint	Date	Sample Collected?	Sample Weight (mg)	Collected On/Off Site
125	M-NS	Enrollment	02-MAY-2001	Yes	330.0	On Site
		Week 1		No		
		Week 2	16-MAY-2001	Yes	800.0	Off Site
		Week 3		No		
		Week 6	18-JUN-2001	Yes	420.0	Off Site
126	M-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
127	M-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
128	M-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
129	M-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
130	M-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630295

Listing 16.5-34
Spontaneous Sputum Collection by Subject
(Page 22 of 23)

Subject Number	Subject Classification ^a	Timepoint	Date	Sample Collected?	Sample Weight (mg)	Collected On/Off Site
131	M-NS	Enrollment		No		
		Week 1		No		
		Week 2	14-MAY-2001	Yes	250.0	On Site
		Week 3	21-MAY-2001	Yes	420.0	On Site
		Week 6		No		
132	M-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
133	M-NS	Enrollment	03-MAY-2001	Yes	420.0	On Site
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
134	M-NS	Enrollment	10-MAY-2001	Yes	1190.0	On Site
		Week 1		No		
		Week 2		No		
		Week 3	30-MAY-2001	Yes	260.0	Off Site
		Week 6	18-JUN-2001	Yes	1320.0	Off Site
135	M-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
500	F-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-34
Spontaneous Sputum Collection by Subject
(Page 23 of 23)

Subject Number	Subject Classification ¹	Timepoint	Date	Sample Collected?	Sample Weight (mg)	Collected On/Off Site
501	F-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
502	F-S	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
503	F-S	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
504	F-S	Enrollment		No		
		Week 1		No		
		Week 2	15-MAY-2001	Yes	760.0	Off Site
		Week 3		No		
		Week 6		No		
505	F-NS	Enrollment		No		
		Week 1		No		
		Week 2		No		
		Week 3		No		
		Week 6		No		
506	F-S	Enrollment		No		
		Week 1		No		
		Week 2	17-MAY-2001	Yes	1.1	Off Site
		Week 3		No		
		Week 6		No		

¹ Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-35
Intercurrent Illness by Subject
(Page 1 of 8)

Subject Number	Subject Classification ^a Illness		Onset		Resolved/Changed		Severity
			Date	Time	Date	Time	
001	F-S	None					
002	F-S	URI	20-MAY-2001	12:00	21-JUN-2001	13:20	Mild
003	F-S	None					
004	F-S	URI	29-APR-2001	04:00	17-MAY-2001	12:00	Mild
005	F-S	None					
006	F-S	None					
007	F-S	None					
008	F-S	Allergies OS injury	26-APR-2001 08-JUN-2001	12:00 21:00	25-JUN-2001 25-JUN-2001	16:00 16:00	Mild Mild
009	F-S	None					
010	F-S	None					
011	F-S	Forearm swelling-left	16-MAY-2001	16:30	24-MAY-2001	08:30	Mild
012	F-S	URI	25-APR-2001	06:00	09-MAY-2001	05:00	Mild
013	F-S	Motor vehicle accident	09-MAY-2001	12:00	02-JUL-2001	09:45	Mild
014	F-S	Flare seasonal allergies Indigestion	06-JUN-2001 15-MAY-2001	15:00 Unknown	11-JUN-2001 15-MAY-2001	08:16 Unknown	Mild Mild
015	F-S	Toothache/extraction	06-MAY-2001	Unknown	10-MAY-2001	15:00	Mild
016	F-S	Sinus pressure	29-APR-2001	20:00	06-JUN-2001	07:00	Mild
017	F-S	None					
018	F-S	URI	01-JUN-2001	07:00	12-JUN-2001	11:38	Mild

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630298

Draft 1: 24 July 2002

Page 14951 of 15132

Listing 16.5-35
Intercurrent Illness by Subject
(Page 2 of 8)

Subject Number	Subject Classification ^a	Illness	Onset		Resolved/Changed		Severity
			Date	Time	Date	Time	
019	F-S	None					
020	F-S	URI	01-JUN-2001	06:00	03-JUL-2001	06:15	Mild
021	F-S	Muscle aches	10-MAY-2001	07:30	11-MAY-2001	09:00	Mild
022	F-S	Nasal congestion	04-MAY-2001	17:00	11-MAY-2001	21:00	Mild
023	F-S	URI	20-MAY-2001	14:00	30-MAY-2001	04:00	Mild
024	F-S	None					
025	F-S	Wrist strain left	24-APR-2001	08:00	03-JUL-2001	07:30	Mild
026	F-S	Sinus infection	08-MAY-2001	Unknown	22-MAY-2001	10:00	Mild
027	F-S	URI	05-JUN-2001	03:00	03-JUL-2001	08:15	Mild
028	F-S	None					
029	F-S	None					
030	F-S	None					
031	F-S	None					
032	F-S	Shoulder/arm soreness	09-MAY-2001	15:00	11-JUN-2001	06:00	Mild
033	F-S	Viral bronchitis	24-MAY-2001	Unknown	18-JUN-2001	07:52	Moderate
034	F-S	URI	11-JUN-2001	06:00	09-JUL-2001	10:50	Moderate
035	F-S	Stiff neck	09-JUN-2001	04:00	13-JUN-2001	08:11	Mild
		Nasal congestion	09-JUN-2001	04:00	13-JUN-2001	08:11	Mild
		Chest congestion	09-JUN-2001	04:00	13-JUN-2001	08:11	Mild
036	M-S	None					

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-35
Intercurrent Illness by Subject
(Page 3 of 8)

Subject Number	Subject Classification ^a	Illness	Onset		Resolved/Changed		Severity
			Date	Time	Date	Time	
037	M-S	Viral illness	27-APR-2001	16:00	03-MAY-2001	09:00	Mild
038	M-S	None					
039	M-S	None					
040	M-S	None					
041	M-S	None					
042	M-S	Headache	16-MAY-2001	08:00	16-MAY-2001	09:30	Mild
		Headache	18-MAY-2001	08:00	18-MAY-2001	09:30	Mild
043	M-S	None					
044	M-S	None					
045	M-S	None					
046	M-S	None					
047	M-S	None					
048	M-S	None					
049	M-S	None					
050	M-S	None					
051	M-S	None					
052	M-S	HA	24-MAY-2001	07:45	24-MAY-2001	10:00	Mild
053	M-S	None					
054	M-S	None					
055	M-S	None					

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-35
Intercurrent Illness by Subject
(Page 4 of 8)

Subject Number	Subject Classification ^a	Illness	Onset		Resolved/Changed		Severity
			Date	Time	Date	Time	
056	M-S	URI	17-MAY-2001	17:00	10-JUL-2001	09:55	Mild
057	M-S	None					
058	M-S	None					
059	M-S	None					
060	M-S	None					
061	M-S	Chest congestion Sinus congestion	20-MAY-2001 20-MAY-2001	09:00 09:00	27-MAY-2001 27-MAY-2001	09:00 09:00	Mild Mild
062	M-S	None					
063	M-S	None					
065	M-S	None					
066	M-S	None					
067	M-S	None					
068	M-S	Abscessed tooth	01-MAY-2001	Unknown	07-MAY-2001	Unknown	Mild
069	M-S	URI	01-JUN-2001	14:00	19-JUL-2001	09:05	Mild
071	F-NS	None					
072	F-NS	Cold sore to left nares Conjunctivitis	01-JUN-2001 04-JUN-2001	07:00 07:00	12-JUN-2001 07-JUN-2001	06:57 16:00	Mild Mild
073	F-NS	None					
074	F-NS	Sore throat	11-JUN-2001	09:00	19-JUL-2001	09:10	Mild
075	F-NS	None					

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-35
Intercurrent Illness by Subject
(Page 5 of 8)

Subject Number	Subject Classification ^a	Illness	Onset		Resolved/Changed		Severity
			Date	Time	Date	Time	
076	F-NS	None					
077	F-NS	None					
078	F-NS	None					
079	F-NS	None					
080	F-NS	Rash	29-APR-2001	07:30	01-MAY-2001	11:09	Mild
		Sore throat	06-MAY-2001	16:00	13-MAY-2001	22:00	Mild
		Diarrhea	02-MAY-2001	20:00	05-MAY-2001	06:30	Mild
		Stomach queasiness	02-MAY-2001	20:00	05-MAY-2001	06:30	Mild
081	F-NS	None					
082	F-NS	None					
083	F-NS	Bruising to right elbow	01-MAY-2001	12:00	01-JUN-2001	09:00	Mild
084	F-NS	Viral URI	08-JUN-2001	12:00	11-JUL-2001	11:25	Mild
085	F-NS	None					
086	F-NS	Rhinorrhea	07-MAY-2001	09:00	18-MAY-2001	22:00	Mild
087	F-NS	None					
088	F-NS	None					
089	F-NS	Root canal URI	21-MAY-2001	14:30	30-MAY-2001	14:30	Mild
			29-MAY-2001	09:00	01-JUN-2001	08:00	Mild
090	F-NS	None					
091	F-NS	Chipped tooth	22-MAY-2001	09:00	22-JUN-2001	Unknown	Mild
092	F-NS	None					

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-35
Intercurrent Illness by Subject
(Page 6 of 8)

Subject Number	Subject Classification*	Illness	Onset		Resolved/Changed		Severity
			Date	Time	Date	Time	
093	F-NS	None					
094	F-NS	Light headed Sunburn	10-MAY-2001 09-JUN-2001	07:20 14:00	10-MAY-2001 13-JUL-2001	07:22 09:50	Mild Mild
095	F-NS	None					
096	F-NS	None					
097	F-NS	None					
098	F-NS	None					
099	F-NS	None					
100	F-NS	None					
101	F-NS	Right antecubital bruising Left antecubital bruising	04-MAY-2001 14-MAY-2001	09:00 07:00	15-MAY-2001 15-MAY-2001	09:00 09:00	Mild Mild
102	F-NS	None					
103	F-NS	None					
104	M-NS	Headache, fever	08-JUN-2001	22:00	09-JUN-2001	10:00	Mild
105	M-NS	Gastroenteritis	14-MAY-2001	08:00	15-MAY-2001	14:45	Mild
106	M-NS	None					
107	M-NS	None					
108	M-NS	None					
109	M-NS	Laceration, scalp	12-MAY-2001	15:00	11-JUN-2001	Unknown	Mild
110	M-NS	None					

* Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630303

Listing 16.5-35
Intercurrent Illness by Subject
(Page 7 of 8)

Subject Number	Subject Classification ^a	Illness	Onset		Resolved/Changed		Severity
			Date	Time	Date	Time	
111	M-NS	None					
112	M-NS	None					
113	M-NS	None					
114	M-NS	None					
115	M-NS	None					
116	M-NS	URI	07-JUN-2001	19:00	08-JUN-2001	08:00	Mild
117	M-NS	None					
118	M-NS	None					
119	M-NS	None					
120	M-NS	None					
121	M-NS	None					
122	M-NS	Nasal congestion	08-MAY-2001	Unknown	08-MAY-2001	Unknown	Mild
123	M-NS	None					
124	M-NS	None					
125	M-NS	Back pain	12-MAY-2001	22:00	13-MAY-2001	08:30	Mild
		Migraine	11-JUN-2001	06:00	14-JUN-2001	15:00	Mild
		Emesis	11-JUN-2001	16:00	11-JUN-2001	16:01	Moderate
126	M-NS	None					
127	M-NS	None					
128	M-NS	Headache	08-MAY-2001	05:45	08-MAY-2001	07:00	Mild

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-35
Intercurrent Illness by Subject
(Page 8 of 8)

Subject Number	Subject Classification ^a	Illness	Onset		Resolved/Changed		Severity
			Date	Time	Date	Time	
129	M-NS	None					
130	M-NS	None					
131	M-NS	Nasal congestion	07-MAY-2001	18:00	12-MAY-2001	07:00	Mild
132	M-NS	None					
133	M-NS	Body aches Nausea	08-MAY-2001 08-MAY-2001	18:00 18:00	09-MAY-2001 09-MAY-2001	06:00 06:00	Mild Mild
134	M-NS	Broken finger Headache	21-APR-2001 27-MAY-2001	15:30 15:00	17-JUL-2001 27-MAY-2001	15:05 15:30	Mild Mild
135	M-NS	Chest congestion	29-APR-2001	07:00	12-JUN-2001	13:54	Mild
500	F-NS	None					
501	F-NS	None					
502	F-S	None					
503	F-S	Nasal congestion Sore throat	17-MAY-2001 17-MAY-2001	11:00 11:00	20-MAY-2001 20-MAY-2001	11:00 11:00	Mild Mild
504	F-S	None					
505	F-NS	Left finger (ring) laceration	26-APR-2001	16:00	28-JUN-2001	13:50	Mild
506	F-S	Migraine	05-JUN-2001	06:00	07-JUN-2001	06:30	Moderate

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 1 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
001	F-S	294.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
002	F-S	159.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
003	F-S	198.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 2 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
004	F-S	130.4	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
005	F-S	282.5	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
006	F-S	139.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 3 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
007	F-S	160.2	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
008	F-S	222.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
009	F-S	162.5	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 4 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
010	F-S	145.4	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
011	F-S	182.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
012	F-S	167.2	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 5 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
013	F-S	178.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	Grade 1/6 systolic murmur
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No
014	F-S	146.5	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No
015	F-S	175.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 6 of 47)

Subject Number	Subject Classification*	Weight (lb)	System	Finding
016	F-S	148.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No
017	F-S	131.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No
018	F-S	123.0	General Appearance	No
			Skin	Erythematous, mildly raised scaling psoriatic patches both elbows and right and left anterior legs, two on right pretibial area, one on left pretibial area
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	Faint short systolic ejection murmur
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

* Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 7 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
019	F-S	238.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
020	F-S	111.6	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
021	F-S	118.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 8 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
022	F-S	225.0	General Appearance	Moderate exogenous obesity
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
023	F-S	127.2	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	Small shotty non-tender anterior cervical lymph nodes palpable bilaterally
024	F-S	198.0	General Appearance	Exogenous obesity
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 9 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
025	F-S	203.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	Missing most of left foot - wearing prosthesis which extends above knee
			Neurological	No
			Lymph Nodes	No
			Other	No
026	F-S	183.2	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No
027	F-S	113.2	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 10 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
028	F-S	120.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
029	F-S	144.0	General Appearance	No
			Skin	No
			HEENT	Tympanic membrane obscured by cerumen
			Mouth	No
			Neck	Diffuse mildly enlarged thyroid gland, non-nodular, (no bruit)
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
030	F-S	198.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 11 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
031	F-S	153.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	Foreshortened forearms - congenital
			Neurological	No
			Lymph Nodes	No
032	F-S	252.0	Other	No
			General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
033	F-S	167.0	Lymph Nodes	No
			Other	No
			General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 12 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
034	F-S	159.2	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No
035	F-S	189.2	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No
036	M-S	175.6	General Appearance	No
			Skin	Actinic keratosis right eyebrow
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 13 of 47)

Subject Number	Subject Classification*	Weight (lb)	System	Finding
037	M-S	172.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	Red throat
			Neck	No
			Thorax/Lungs	Wheezes left upper and lower lung fields posteriorly
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No
038	M-S	212.2	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	Teeth with poor repair
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No
039	M-S	186.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	Dentures - upper and lower
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

* Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.3-36
Enrollment Physical Examination by Subject
(Page 14 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
040	M-S	168.5	General Appearance	No
			Skin	No
			HEENT	Contacts
			Mouth	Status post wisdom teeth removal
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No
041	M-S	155.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No
042	M-S	304.0	General Appearance	No
			Skin	No
			HEENT	Glasses
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 15 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
043	M-S	148.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No
044	M-S	186.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No
045	M-S	132.5	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	Small shotty nontender anterior cervical lymph nodes palpable bilaterally - NCS
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

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Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 16 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
046	M-S	168.0	General Appearance	No
			Skin	No
			HEENT	Right tympanic membrane obscured by cerumen
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	Systolic ejection murmur grade 1-2/6
			Abdomen	No
			Musculoskeletal	Mild pectus excavatum noted
			Neurological	No
			Lymph Nodes	No
			Other	No
047	M-S	163.4	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No
048	M-S	190.2	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.3-36
Enrollment Physical Examination by Subject
(Page 17 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
049	M-S	181.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	Grade II/VI systolic murmur
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No
050	M-S	134.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	All upper teeth absent (extracted) and multiple lower teeth extracted
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	Small shotty right and left nontender anterior cervical lymph nodes palpable bilaterally
			Other	No
051	M-S	164.0	General Appearance	No
			Skin	Acne lesions-generalized to upper trunk
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 18 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
052	M-S	190.8	General Appearance	No
			Skin	No
			HEENT	Left tympanic membrane obscured by cerumen
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	Mild pectus excavatum
			Neurological	No
			Lymph Nodes	No
			Other	No
053	M-S	169.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No
054	M-S	208.5	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 19 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
055	M-S	214.0	General Appearance	Mild - moderate obesity
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	Left ankle mildly swollen; walks with limp
			Neurological	Mild bilateral intention tremor
			Lymph Nodes	No
056	M-S	138.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	Poor dentition with multiple lower and upper teeth missing (extracted)
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	Short soft grade 2/6 systolic ejection murmur at cardiac apex and lower sternal border, not clinically significant
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	Small, shotty, non tender anterior cervical lymph nodes palpable bilaterally
057	M-S	257.2	General Appearance	Exogenous obesity
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 20 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
058	M-S	197.2	General Appearance	No
			Skin	No
			HEFNT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No
059	M-S	127.8	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	Small, non tender anterior cervical lymph nodes palpable bilaterally
			Other	No
060	M-S	224.0	General Appearance	Mild - moderate obesity
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	Bilateral mild intention tremor both hands on finger - finger and finger - to - nose testing
			Lymph Nodes	No
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630325

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 21 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
061	M-S	185.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
062	M-S	199.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
063	M-S	213.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 22 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
065	M-S	175.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No
066	M-S	161.2	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No
067	M-S	184.0	General Appearance	No
			Skin	No
			HEENT	Right eye limited range of motion
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 23 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
068	M-S	164.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
069	M-S	174.4	Other	No
			General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
071	F-NS	206.0	Lymph Nodes	No
			Other	No
			General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 24 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
072	F-NS	149.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No
073	F-NS	165.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	Missing wisdom teeth
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No
074	F-NS	160.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	Wisdom teeth gone
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 25 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
075	F-NS	214.4	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
076	F-NS	158.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	Wisdom teeth and tonsils removed
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
077	F-NS	151.8	General Appearance	No
			Skin	No
			HEENT	Tonsils and adenoids removed
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 26 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
078	F-NS	148.5	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
079	F-NS	138.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
080	F-NS	221.0	General Appearance	No
			Skin	Poison ivy rash (resolving)
			HEENT	No
			Mouth	Status post tonsils
			Neck	7th cervical discectomy
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	Multiple foot surgeries; bunions
			Neurological	No
			Lymph Nodes	No
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.S-36
Enrollment Physical Examination by Subject
(Page 27 of 47)

Subject Number	Subject Classification*	Weight (lb)	System	Finding
081	F-NS	136.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
082	F-NS	144.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
083	F-NS	131.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

* Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630332

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 28 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
084	F-NS	171.0	General Appearance	No
			Skin	No
			HEENT	Exudates (drusen) both retinas
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
085	F-NS	128.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
086	F-NS	185.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 29 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
087	F-NS	174.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	Faint short grade 1/6 systolic ejection murmur at cardiac apex
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No
088	F-NS	182.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No
089	F-NS	154.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

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Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 30 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
090	F-NS	186.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	Grade II/VI systolic murmur
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No
091	F-NS	150.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	Osteoarthritis changes hands
			Neurological	No
			Lymph Nodes	No
			Other	No
092	F-NS	191.0	General Appearance	Moderate exogenous obesity
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630335

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 31 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
093	F-NS	138.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
094	F-NS	116.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	Grade 1/6 systolic ejection murmur
			Abdomen	No
			Musculoskeletal	Mild pectus excavatum
			Neurological	No
			Lymph Nodes	No
095	F-NS	175.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 32 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
096	F-NS	149.6	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
097	F-NS	175.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
098	F-NS	138.2	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	Faint short grade 1/6 systolic ejection murmur at cardiac apex - NCS
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 33 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
099	F-NS	128.0	General Appearance	No
			Skin	No
			HEENT	Small amount of punctate white exudate on left tonsil
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	Small shotty non tender anterior cervical lymph nodes palpable bilaterally
			Other	No
100	F-NS	121.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No
101	F-NS	158.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 34 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
102	F-NS	182.0	General Appearance	Moderate obesity
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No
103	F-NS	209.0	General Appearance	Exogenous obesity - moderate
			Skin	Mild facial acne
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No
104	M-NS	141.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 35 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
105	M-NS	180.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No
106	M-NS	160.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	Wisdom teeth removed
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No
107	M-NS	210.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630340

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 36 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
108	M-NS	174.2	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
109	M-NS	176.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
110	M-NS	204.5	General Appearance	No
			Skin	No
			HEENT	Glasses
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630341

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 37 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
111	M-NS	206.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	Grade 1/6 systolic ejection murmur
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
112	M-NS	181.1	Other	No
			General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	Right inguinal hernia
			Musculoskeletal	No
			Neurological	No
113	M-NS	192.4	Lymph Nodes	No
			Other	No
			General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 38 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
114	M-NS	179.2	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
115	M-NS	146.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
116	M-NS	159.2	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630343

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 39 of 47)

Subject Number	Subject Classification*	Weight (lb)	System	Finding
117	M-NS	144.8	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No
118	M-NS	192.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	Lumbar discs removed L3, L4
			Neurological	No
			Lymph Nodes	No
			Other	No
119	M-NS	270.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	Decreased deep tendon reflex right knee
			Lymph Nodes	No
			Other	No

* Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630344

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 40 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
120	M-NS	166.0	General Appearance	No
			Skin	No
			HEENT	Both tympanic membranes obscured by cerumen
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	Faint short grade 1/6 systolic ejection murmur at upper left sternal border
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No
121	M-NS	155.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	Small shotty non-tender anterior lymph nodes palpable bilaterally, one on each side
			Other	No
122	M-NS	140.6	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 41 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
123	M-NS	180.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
124	M-NS	184.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
125	M-NS	216.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 42 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
126	M-NS	208.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	Pectus excoriation, not clinically significant
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No
127	M-NS	179.4	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No
128	M-NS	206.2	General Appearance	No
			Skin	Glasses
			HEENT	Ear wax
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 43 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
129	M-NS	177.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	Very short soft grade 1-2/6 systolic ejection murmur at lower sternal border - functional and not clinically significant
			Abdomen	No
			Musculoskeletal	Mild pectus excavatum
			Neurological	No
			Lymph Nodes	No
130	M-NS	169.4	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
131	M-NS	166.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 44 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
132	M-NS	170.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	Soft physiologic S3 at cardiac apex (no murmur)
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No
133	M-NS	151.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No
134	M-NS	138.0	General Appearance	No
			Skin	No
			HEENT	Ptosis of left eye (congenital)
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	Palpable lymph node to anterior cervical area
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 45 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
135	M-NS	139.4	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	Hernia repair right inguinal
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No
500	F-NS	234.0	General Appearance	No
			Skin	No
			HEENT	Glasses
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No
501	F-NS	158.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	Systolic ejection murmur II of V1 consistent with mitral valve prolapse and click
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 46 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
502	F-S	154.8	General Appearance	Mild obesity
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
503	F-S	143.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
504	F-S	120.5	General Appearance	No
			Skin	No
			HEENT	Teeth in poor repair
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-36
Enrollment Physical Examination by Subject
(Page 47 of 47)

Subject Number	Subject Classification ^a	Weight (lb)	System	Finding
503	F-NS	130.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	4 sutures on left ring finger
			Neurological	No
			Lymph Nodes	No
			Other	No
506	F-S	155.0	General Appearance	No
			Skin	No
			HEENT	No
			Mouth	No
			Neck	No
			Thorax/Lungs	No
			Cardiovascular	No
			Abdomen	No
			Musculoskeletal	No
			Neurological	No
			Lymph Nodes	No
			Other	No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630352

Listing 16.3-37
Medical History by Subject
(Page 1 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
001	F-S	Skin	1986	C	Acne breakouts
		EENT	1988	C	Astigmatism
			1986	C	Myopia
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No
		Musculoskeletal			No
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
002	F-S	Allergic			No
		Other			NA
		Skin			No
		EENT	1978	R	Wisdom teeth extraction
			1979	R	Tonsillectomy
		Breasts			No
		Respiratory			No
		Cardiovascular	1991	C	Hypertension
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary	1996	R	Kidney stones
			Unknown	R	UTI's
		Musculoskeletal			No
		Endocrine			No
003	F-S	Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
		Skin	1993	C	Acne
		EENT			No
		Breasts			No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630353

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-37
Medical History by Subject
(Page 2 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
003	F-S	Respiratory	1999	R	No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No
		Musculoskeletal			Sprained ankle
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
004	F-S	Skin	1996	C	Dermatitis
		EENT	1978	C	Myopia
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary	JAN-1992	R	Endometriosis
			1998	C	Postmenopausal
		Musculoskeletal			No
		Endocrine	1992	R	Gestational diabetes
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic	1980	C	Allergic to nickel and rabbit fur
		Other			NA
005	F-S	Skin	NOV-2000	R	No
		EENT			No
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			UTI

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.^b R=Resolved, C=Continuing.

PM3006630354

Listing 16.5-37
Medical History by Subject
(Page 3 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
005	F-S	Genitourinary Musculoskeletal Endocrine Neurological Immunological Psychological Allergic Other	Unknown	R	Pregnancy with delivery x 3, 3 full term pregnancies No No No No No No No NA
006	F-S	Skin EENT Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal Endocrine Neurological Immunological Psychological Allergic Other	 1962 1997 1972 1986 1998 1997 1987 1995 1983 1962 1973 1972	 C C R C C R C R R R C C	No Myopia Presbyopia 4 wisdom teeth extracted Fibrocystic breasts SOB on exertion Bronchitis x 2 Varicosities right leg No Stomach pain UTI Edema/pain right knee No Hand tremors with coffee intake No Depression No NA
007	F-S	Skin EENT Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal Endocrine	1997 1992 1987 1990 1990	R C R R C	Plastic surgery-abdomen Myopia Bilateral breast reduction No No No No Radical hysterectomy No Postmenopausal

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630355

Listing 16.5-37
 Medical History by Subject
 (Page 4 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
007	F-S	Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
008	F-S	Skin			No
		EENT			No
		Breasts			No
		Respiratory	1969	R	Pneumonia x 4
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary	FEB-2001	R	Pelvic infection
			1992	R	Tubal ligation
			1985	R	Abnormal pap smears-cryo surgery
			28-APR-2001	C	Spotting from Depo-provera
		Musculoskeletal	2000	R	Carpal tunnel surgery
		Endocrine			No
		Neurological	1991	R	Viral encephalitis
			1991	C	Migraines
		Immunological			No
		Psychological			No
		Allergic	1988	C	Sulfa allergy
			1968	C	Rash from Ivory soap
			1990	C	Intolerance to erythromycin
			1988	C	PCN allergy
		Other			NA
009	F-S	Skin			No
		EENT	1948	C	Myopia
			1980	C	Presbyopia
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary	1967	R	Kidney stone

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

Listing 16.5-37
Medical History by Subject
(Page 5 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
009	F-S	Genitourinary	1975	R	Tubal ligation
			1987	R	Fx right wrist
			1989	R	Fx right ankle
			1997	R	Fx left ankle
			2000	R	Fx 5th digit right hand
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
010	F-S	Skin	1990	R	Cyst on upper lip removed
		EENT			No
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No
		Musculoskeletal	1988	R	Fracture of collarbone
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
		Skin			No
011	F-S	EENT	1992	C	Presbyopia
			1971	R	Crowded wisdom teeth x 4
			1953	R	Tonsillitis
		Breasts	1987	R	Fibrocystic lump bilaterally x 2
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary	1973	R	Tubal ligation

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630357

Listing 16.S-37
Medical History by Subject
(Page 6 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
011	F-S	Genitourinary	1966	R	Spontaneous abortion
		Musculoskeletal	1987	R	Herniated disk
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
012	F-S	Skin			No
		EENT			Impacted wisdom teeth
			1995	R	Multiple fractures of nose and cracked cheek bones
			Unknown	R	Tooth infection
			MAR-2001	R	No
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No
		Musculoskeletal			No
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic	1994	C	Erythromycin intolerance
		Other			NA
013	F-S	Skin			No
		EENT	1989	R	Wisdom teeth extracted
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary	MAY-1998	R	Induced abortion
			SEP-2000	R	UTI
		Musculoskeletal	1980	R	Wrist fracture
		Endocrine			No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630358

Listing 16.5-37
Medical History by Subject
(Page 7 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
013	F-S	Neurological Immunological Psychological Allergic Other	1994	R	No No Counselling secondary to divorce No NA
014	F-S	Skin EENT Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal Endocrine Neurological Immunological Psychological Allergic Other	2001 1971 MAR-2001 1991 1978 1998	C R C C C C	No Presbyopia No No No No No Irregular menstrual cycles Torn ligament - right ankle Generalized aches and pains No No No Insomnia with stress Seasonal allergies NA
015	F-S	Skin EENT Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal Endocrine Neurological Immunological Psychological Allergic Other	1970	R	No No No Bronchitis No No No No No No No No No No NA

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630359

Listing 16.5-37
Medical History by Subject
(Page 8 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
016	F-S	Skin	1996	C	Acne
			1966	R	Tonsillectomy
			1981	R	Extraction of 2 infected wisdom teeth
			1965	C	Myopia
		Breasts			No
		Respiratory	1988	R	Bronchitis
		Cardiovascular	1997	C	Heart murmur
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary	1984	R	C-section
			1992	R	Tubal ligation
			1993	R	Kidney stones/lithotripsy
		Musculoskeletal			No
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
017	F-S	Skin			No
		EENT	1978	R	Wisdom teeth extracted
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary	1999	R	Abnormal pap smear
					No
		Musculoskeletal			No
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
018	F-S	Skin	1977	C	Psoriasis-most common occurrences to elbows and shin, last outbreak 1991
		EENT	1991	R	Tonsillectomy

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.^b R=Resolved, C=Continuing.

PM3006630360

Listing 16.5-37
Medical History by Subject
(Page 9 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
018	F-S	Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal Endocrine Neurological Immunological Psychological Allergic Other	1990	R	No No No Mononucleosis No No No No No No No No No NA
019	F-S	Skin EENT Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal Endocrine Neurological Immunological Psychological Allergic Other	1998 1995 1978 1995 1992	C R R C C	Dry skin patch on neck Wisdom teeth removed No No No No No No Fractured left arm No No No No Allergy-codeine Allergy-motrin NA
020	F-S	Skin EENT Breasts Respiratory Cardiovascular Lymphatic/Hematologic	1978 MAR-2001	C R	No Myopia Tooth extraction No No No No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630361

Listing 16.5-37
Medical History by Subject
(Page 10 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
020	F-S	Gastrointestinal	1982	R	No
		Genitourinary			No
		Musculoskeletal			Wrist Fx
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
021	F-S	Other	1998	C	NA
		Skin			No
		EENT			Presbyopia
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary	1979	R	No
		Musculoskeletal			No
		Endocrine			No
		Neurological			Infant seizures
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
022	F-S	Skin	1995	R	No
		EENT			Extraction of 4 wisdom teeth
		Breasts			No
		Respiratory			No
		Cardiovascular	1987	R	No
		Lymphatic/Hematologic			Mononucleosis
		Gastrointestinal	1994	R	Cholecystectomy due to gallstone(s)
		Genitourinary	1989	R	Laparoscopy for infected fallopian tubes
		Musculoskeletal			No
		Endocrine			No
		Neurological			No
		Immunological			No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630362

Listing 16.5-37
Medical History by Subject
(Page 11 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
022	F-S	Psychological Allergic Other			No No NA
023	F-S	Skin EENT Breasts Respiratory	1958 1958	C R	No No No Asthma Bronchitis-chronic
		Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary	1995 1979	R R	No No No Uterine - benign cysts Elective sterilization-tubal ligation
		Musculoskeletal Endocrine Neurological Immunological Psychological Allergic Other	1981	C	No No No No No Allergies NA
024	F-S	Skin EENT	1977 1976	R R	No Wisdom teeth removal Tonsillectomy and adenoidectomy
		Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary	1989 1989 1996 1994	R R R R	No No No No Appendectomy Cesarean section Urinary tract infection Cesarean section
		Musculoskeletal Endocrine Neurological Immunological Psychological			No No No No No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630363

Listing 16.5-37
Medical History by Subject
(Page 12 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
024	F-S	Allergic Other	1970	C	Penicillin allergy NA
025	F-S	Skin EENT Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal Endocrine Neurological Immunological Psychological Allergic Other	Unknown 1986 1975 1966	C R R R	No Myopia No No No No No Hysterectomy Cesarean section Cesarean section No No No No No No No NA
026	F-S	Skin EENT Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal Endocrine Neurological Immunological Psychological Allergic Other	 1962 1957 APR-2001 1976 1991 1996	 R C C R C C	No Tonsillectomy Myopia No Sinus congestion No No No Tubal ligation Postmenopausal No No No No Depression No NA

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.^b R=Resolved, C=Continuing.

PM3006630364

Listing 16.5-37
Medical History by Subject
(Page 13 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
027	F-S	Skin EENT	16-APR-2001	C	Bubble soap allergy - contact dermatitis
			1965	R	Tonsillectomy
			1989	R	Dental extraction - all upper teeth
			1994	R	Dental extraction - lower set, two teeth
		Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal Endocrine Neurological Immunological Psychological Allergic Other	1987	C	Breast implants bilaterally
					No
					No
					No
			1969	R	Appendectomy
					No
					No
					No
					No
					No
			1989	C	Tetracycline allergy
					NA
028	F-S	Skin EENT			No
			1997	R	Wisdom teeth - extracted
			1997	C	Myopia
		Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal Endocrine Neurological Immunological Psychological Allergic Other			No
					No
					No
					No
					No
					No
					No
					No
					No
					No
					No
					No
					NA
029	F-S	Skin EENT			No
			1999	R	Strep throat infection
			1996	R	Wisdom tooth extracted x4

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630365

Listing 16.5-37
Medical History by Subject
(Page 14 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
029	F-S	Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal Endocrine Neurological Immunological Psychological Allergic Other	1999	C	No No No No No No No No No No No Seasonal allergies NA
030	F-S	Skin EENT Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal Endocrine Neurological Immunological Psychological Allergic Other	1965 1969 1999 1997 1977 1984 08-APR-2001 1989 1985	R R R R R R R R R	No Amblyopia surgery, left eye Tonsillectomy Periodontal dental surgery Sinus surgery x2 Extraction of 4 wisdom teeth No No No No No No No No No No No Myelogram with allergic reaction to procedure dye NA
031	F-S	Skin EENT	1979	R	No Bilateral ear tubes

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630366

Listing 16.5-37
Medical History by Subject
(Page 15 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
031	F-S	EENT	FEB-2000	R	Chronic sinus infections - surgery
			1985	C	Myopia
			1995	R	Wisdom teeth removal
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No
		Musculoskeletal			No
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic	Unknown	C	Allergic to mixed nuts
032	F-S		1985	R	Seasonal allergies
		Other			NA
		Skin			No
		EENT	1994	R	Tonsillectomy & adenoidectomy
			1992	R	Wisdom teeth extracted
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal	1999	R	Laparoscopic cholecystectomy
		Genitourinary			No
		Musculoskeletal	1988	R	Right ankle Fx
			1982	C	Loss of digit - right pinky
		Endocrine			No
		Neurological			No
033	F-S	Immunological			No
		Psychological	NOV-2000	C	Post partum depression
		Allergic	1990	C	PCN allergy
		Other			NA
		Skin			No
		EENT			No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630367

Listing 16.5-37
Medical History by Subject
(Page 16 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
033	F-S	Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No
		Musculoskeletal			No
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
034	F-S	Skin			No
		EENT	1998	C	Presbyopia
		Breasts			No
		Respiratory	1995	R	Bronchitis
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal	1991	C	Hemorrhoids
		Genitourinary	1991	R	C-section
			1993	R	Cone biopsy
		Musculoskeletal			No
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological	1992	R	Depression, anxiety
			1999	C	Depression
		Allergic	1995	C	Metal allergy
			1986	C	Dust, mold allergy
		Other			NA
035	F-S	Skin			No
		EENT	1963	R	Tonsillectomy and adenoidectomy
			1967	R	Ear infections
		Breasts			No
		Respiratory			No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630368

Listing 16.5-37
 Medical History by Subject
 (Page 17 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
035	F-S	Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary	2000	R	Hysterectomy
			1994	R	Fibroid tumors
		Musculoskeletal	1971	R	Right ankle Fx
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
036	M-S	Skin	01-MAY-2001	C	Actinic keratosis right eyebrow
		EENT	1970	C	Myopia
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No
		Musculoskeletal	MAR-2001	C	Sprained right wrist
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
037	M-S	Skin			No
		EENT	JAN-2001	R	Wisdom teeth extracted
			20-MAR-2001	R	Pink eye, right eye
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No
					No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630369

Listing 16.5-37
Medical History by Subject
(Page 18 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
037	M-S	Musculoskeletal Endocrine Neurological Immunological Psychological Allergic Other			No No No No No No NA
038	M-S	Skin EENT Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal Endocrine Neurological Immunological Psychological Allergic Other	1977	C	No Myopia No No No No No No No No No No No No NA
039	M-S	Skin EENT Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal Endocrine	1951 1990 2000 1976 1999 1996 1996 1999 2000	C R R R R R R C C	No Myopia No No No No Appendectomy Colonic polyps Vasectomy Fx ankle Degenerative disks - neck Surgical repair of neck disks Back pain Hypercholesterolemia

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630370

Listing 16.5-37
Medical History by Subject
(Page 19 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
039	M-S	Neurological Immunological Psychological Allergic Other			No No No No NA
040	M-S	Skin EENT Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal Endocrine Neurological Immunological Psychological Allergic Other	1995 1988 1998 1999 1987 1998	R C C R R C	No Four impacted wisdom teeth Myopia No No No No No Router injury finger left hand Fracture left arm Fracture left arm No No No No Sulfa NA
041	M-S	Skin EENT Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal Endocrine Neurological Immunological Psychological			No No No No No No No No No No No No No No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.^b R=Resolved, C=Continuing.

PM3006630371

Listing 16.5-37
Medical History by Subject
(Page 20 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
041	M-S	Allergic Other			No NA
042	M-S	Skin EENT Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal Endocrine Neurological Immunological Psychological Allergic Other	1992 1987 1985 1994 1981	R C R R C	Acne Myopia No No No No No No No Fracture arm/wrist left Dislocated left shoulder No No No No Animal hair allergy NA
043	M-S	Skin EENT Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal Endocrine Neurological Immunological Psychological Allergic Other			No No No No No No No No No No No No No No No NA
044	M-S	Skin EENT	1976	C	No Myopia

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630372

Listing 16.5-37
Medical History by Subject
(Page 21 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
044	M-S	EENT	1986	R	Wisdom teeth extracted
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal	1973	R	Umbilical hernia
		Genitourinary			No
		Musculoskeletal			No
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic	1975	C	Hayfever
		Other			NA
045	M-S	Skin			No
		EENT			No
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No
		Musculoskeletal			No
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
046	M-S	Skin			No
		EENT	1984	R	Adenoids removed
			1987	R	Molars removed
			1987	C	Myopia
		Breasts			No
		Respiratory			No
		Cardiovascular			No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630373

Listing 16.5-37
Medical History by Subject
(Page 22 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
046	M-S	Lymphatic/Hematologic			No
		Gastrointestinal	1982	R	Appendectomy
			1996	C	Intermittent heartburn
		Genitourinary			No
		Musculoskeletal	1987	R	Fracture left wrist
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic	1990	C	Seasonal allergies
		Other			NA
047	M-S	Skin			No
		EENT			No
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal	1985	R	Appendectomy
		Genitourinary			No
		Musculoskeletal	1999	R	Fx right ankle
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological	NOV-2000	C	Bipolar disorder
			1998	C	Depression
		Allergic			No
		Other			NA
048	M-S	Skin			No
		EENT	1980	R	Otitis media
			1996	R	Wisdom teeth extracted
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No
					No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630374

Listing 16.5-37
Medical History by Subject
(Page 23 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
048	M-S	Musculoskeletal	1988	R	Fx collar bone
			1997	R	Surgical repair of hand caught in conveyer belt
			1999	R	Arthroscopic surgery right knee
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
049	M-S	Allergic			No
		Other			NA
		Skin			No
		EENT			No
		Breasts			No
		Respiratory			No
		Cardiovascular	1999	R	Blockage of femoral artery
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No
		Musculoskeletal	1950	R	Fractured little finger of right hand, left hand and left thumb
			1948	C	No cartilage right knee
			1999	C	Arthritis right knee, left ankle, left wrist
			2000	C	Hypercholesterolemia
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
050	M-S	Skin	1971	R	Laceration left palm
		EENT			No
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No
		Musculoskeletal	MAR-2001	C	Epicondylitis
		Endocrine			No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

Listing 16.5-37
Medical History by Subject
(Page 74 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
050	M-S	Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
051	M-S	Skin			No
		EENT			No
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No
		Musculoskeletal			No
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
052	M-S	Skin	1985	R	Laceration right eyebrow
			JUL-1989	R	Poison oak
		EENT	1986	C	Myopia
			1988	R	Wisdom teeth extracted
		Breasts			No
		Respiratory	MAY-1997	R	Bronchitis
			JAN 2001	R	Bronchitis
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal	1995	C	Hemorrhoids
		Genitourinary	1991	R	Unknown GU problem, tx with abx
		Musculoskeletal	1989	R	Fx left metacarpal
			1980	R	Fx right patella
			1988	R	Fx right 1st toe
			1980	R	Trauma to left knee
		Endocrine			No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630376

Listing 16.5-37
Medical History by Subject
(Page 25 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
052	M-S	Neurological Immunological Psychological Allergic Other			No No No No NA
053	M-S	Skin EENT Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal	JAN-2000 APR-2001	R C	No No No No No No No No No Fx right ankle Left shoulder pain
		Endocrine Neurological Immunological Psychological Allergic Other			No No No No No NA
054	M-S	Skin EENT Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal	1982 1990 1999 1996 1995 1994	R R R R R	No Tonsils-infection - tonsillectomy, No No No No Food poisoning No Dislocation/torn ligament of left knee Fracture left collar bone Fracture right hip Fracture right hip
		Endocrine Neurological Immunological			No No No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630377

Listing 16.5-37
Medical History by Subject
(Page 26 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
054	M-S	Psychological Allergic Other	1979	C	No Allergies - seasonal NA
055	M-S	Skin EENT Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal Endocrine Neurological Immunological Psychological Allergic Other	1985 29-OCT-2000 DEC-2000	R R R	No Wisdom teeth extraction No No No No No No Left leg/ankle pylon fracture Left leg/ankle infection No No No No No NA
056	M-S	Skin EENT Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal Endocrine Neurological Immunological Psychological Allergic Other	1998 1991 1996	C R C	No Dental caries No No No No No No No Fx of jaw No No No No Bee sting allergy NA
057	M-S	Skin			No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630378

Listing 16.5-37
Medical History by Subject
(Page 27 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
057	M-S	EENT	1987	C	Myopia
			1979	R	Esophageal surgery
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No
		Musculoskeletal			No
		Endocrine			No
		Neurological	1984	R	Possible meningitis
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
058	M-S	Skin			No
		EENT			No
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No
		Musculoskeletal			No
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
059	M-S	Skin	MAR-1995	R	Laceration and sutured right first finger
		EENT	1969	R	Tonsillectomy
			1979	R	Wisdom teeth extracted
			1968	C	Myopia
		Breasts			No
		Respiratory			No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

Listing 16.5-37
Medical History by Subject
(Page 28 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
059	M-S	Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary	1997	R	Elective sterilization - vasectomy
		Musculoskeletal	1983	R	Fracture right wrist - casted
			1998	R	Hyperextension of 2 middle fingers of right hand - splinted
			1982	R	Strained left knee muscles - crutches
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
060	M-S	Skin			No
		EENT			No
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No
		Musculoskeletal			No
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
061	M-S	Skin	1988	R	Laceration to top of head
		EENT			No
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630380

Listing 16.5-37
Medical History by Subject
(Page 29 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
061	M-S	Musculoskeletal	1998	R	Phlebitis left leg
		Endocrine			No
		Neurological	1988	R	Loss of consciousness secondary to laceration of head
		Immunological			No
		Psychological			No
		Allergic	1988	C	Allergy to penicillin
062	M-S		1998	C	Allergy to cephalosporins
		Other			NA
		Skin			No
		EENT	1959	C	Legally blind in left eye
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No
		Musculoskeletal			No
		Endocrine			No
		Neurological	1992	R	Frequent severe headaches over left eye
		Immunological			No
		Psychological	1995	C	Bi-polar disorder
		Allergic			No
		Other			NA
063	M-S	Skin			No
		EENT			No
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No
		Musculoskeletal	1981	R	Fractured right femur
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630381

Listing 16.5-37
Medical History by Subject
(Page 30 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
063	M-S	Allergic	1988	C	Allergy to penicillin
			1982	C	Seasonal allergies
			1980	C	Allergic to raw apples, nuts, and deoderants
065	M-S	Other			NA
		Skin			No
		EENT	1999	R	4 wisdom teeth extracted
			1986	R	Adenoidectomy
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No
		Musculoskeletal			No
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
066	M-S	Skin			No
		EENT	23-APR-2001	R	Tooth extraction
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal	1971	R	Hepatitis A - 1971 & 1977
		Genitourinary			No
		Musculoskeletal	1986	R	Left shoulder, bilateral hands - ligaments torn
			1986	R	OS orbital fx
			1986	R	Rib fx
			1991	R	Fx tibia and fibula
		Endocrine			No
		Neurological	1976	R	Concussion
		Immunological			No
		Psychological			No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630382

Listing 16.5-37
Medical History by Subject
(Page 31 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
066	M-S	Allergic Other			No NA
067	M-S	Skin EENT	1984 2000	R R	No Surgical repair of right eye orbit Removed wisdom teeth
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No
		Musculoskeletal			No
		Endocrine			No
		Neurological	1984	R	Loss of consciousness from eye injury
		Immunological			No
		Psychological			No
		Allergic	1991 1985	C C	Reaction to certain soaps Allergy to penicillin
		Other			NA
068	M-S	Skin EENT Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal Endocrine Neurological Immunological Psychological Allergic Other	16-APR-2001	C	No No No No No No No No No Pulled muscle in back No No No No No NA
069	M-S	Skin			No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630383

Listing 16.5-37
Medical History by Subject
(Page 32 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
069	M-S	EENT	1987	C	Myopia
			MAR-2001	C	Impacted wisdom teeth / mouth infection
		Breasts			No
		Respiratory	1998	R	Bronchitis
			1983	R	Pneumonia
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No
		Musculoskeletal	1979	R	Right forearm fracture
			1981	R	Right index finger fracture
			1998	R	Left hand fracture
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
071	F-NS	Skin	1983	R	Laceration left knee
			1982	R	Laceration right thigh
			1979	R	Laceration lower lip
			1999	C	Rash left arm
			1996	C	Myopia
		EENT			
		Breasts	OCT-2000	R	Biopsy - lump left breast found benign
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary	2000	C	Irregular menstrual cycles
		Musculoskeletal	1982	R	Fracture right arm
		Endocrine			No
		Neurological	1983	R	Loss of consciousness with concussion
		Immunological			No
		Psychological			No
		Allergic	1982	C	Bee sting allergy
			1999	C	Mold allergy
		Other			NA

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630384

Listing 16.5-37
Medical History by Subject
(Page 33 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
072	F-NS	Skin	1964	R	Second or third degree burn on left anterior shoulder left side of chest and upper medial portion of neck
			1992	C	Intermittent cold sores
		EEENT			No
		Breasts			No
		Respiratory	1978	C	Asthma
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No
		Musculoskeletal			No
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
073	F-NS	Skin	1999	R	Burn to right forearm
		EEENT			No
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No
		Musculoskeletal			No
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic	1993	C	Allergic to animal dander and dust
		Other			NA
074	F-NS	Skin	2000	C	Eczema in winter
		EEENT	1999	R	Pierced ear drum
			2000	R	Wisdom teeth extraction
		Breasts			No
		Respiratory			No

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^b R=Resolved, C=Continuing.

PM3006630385

Listing 16.5-37
Medical History by Subject
(Page 34 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
074	F-NS	Cardiovascular	FEB-2001	C	No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			Breakthrough bleeding
		Musculoskeletal			No
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
075	F-NS	Skin			No
		EENT			No
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No
		Musculoskeletal			No
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
076	F-NS	Skin	APR-1990	R	No
		EENT			Wisdom teeth extracted
			1989	R	Tonsillectomy
		Breasts	Unknown	R	No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			Stomach ache due to eating spicy food
		Genitourinary	06-OCT-2000	R	Abnormal pap smear x2
		Musculoskeletal	1984	R	Fractured little finger left hand

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630386

Listing 16.5-37
Medical History by Subject
(Page 35 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
076	F-NS	Endocrine	1992	C	No
		Neurological			Headaches
		Immunological			No
		Psychological	Unknown	C	No
		Allergic			Cat dander allergy
		Other			NA
077	F-NS	Skin	1991	R	Mole removal left arm
		EENT	1979	R	Ear tube placement
			1979	R	Adenoidectomy, tonsillectomy
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No
		Musculoskeletal			No
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
078	F-NS	Skin	1978	R	Facial acne
		EENT	1983	C	Myopia
			1986	R	Two impacted wisdom teeth/removal
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary	1997	R	Laparoscopy
		Musculoskeletal			No
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
					No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630387

Listing 16.5-37
Medical History by Subject
(Page 36 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
078	F-NS	Allergic Other	1996	C	Seasonal allergies NA
079	F-NS	Skin EENT Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal Endocrine Neurological Immunological Psychological Allergic Other	1996 1992 1978 1972	C C R R	No No Fibrocystic breasts No Varicose veins No No Tubal ligation History of urinary tract infections No No No No No No NA
080	F-NS	Skin EENT Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal Endocrine Neurological Immunological Psychological Allergic Other	1970 1958 DEC-2000 MAY-1999 1996 1999	R C R R C C	No Tonsillectomy Myopia No No No No No No Bunionectomy Microdiscectomy Bilateral shoulder pain - arthritis Hypercholesterolemia No No No No NA

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630388

Listing 16.5-37
Medical History by Subject
(Page 37 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
081	F-NS	Skin	1967	R	No
		EENT			Tonsillectomy
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic	1989	R	No
		Gastrointestinal			No
		Genitourinary	1984	R	Cesarean section
		Musculoskeletal			Bilateral bunionectomy
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
082	F-NS	Skin			No
		EENT			No
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No
		Musculoskeletal			No
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic	1971	C	Bee sting allergy
		Other			NA
083	F-NS	Skin	14-APR-2001	C	Laceration on right 5th digit
		EENT	1971	R	Tonsillectomy
			1995	R	Wisdom teeth extraction (4)
		Breasts			No
		Respiratory			No
		Cardiovascular			No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-37
Medical History by Subject
(Page 38 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
083	F-NS	Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary	1987	R	Cesarean section
			1992	R	Right inguinal hernia repair
		Musculoskeletal			No
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
084	F-NS	Skin	1997	R	Hosp for 6 days - IVs/antibiotics (spider bite)
		EENT	1946	R	Tonsillectomy
			1981	C	Presbyopia
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal	1987	C	Heartburn
		Genitourinary	1951	R	Cesarean section
			1953	R	Cesarean section
			1957	R	Cesarean section
		Musculoskeletal	MAY-2000	R	Arthroscopic knee surgery
			1998	Unk.	X-ray shows possible bruise on left rib
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
085	F-NS	Skin			No
		EENT			No
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630390

Draft 1: 24 July 2002

Page 15043 of 15132

Listing 16.5-37
Medical History by Subject
(Page 39 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
085	F-NS	Gastrointestinal Genitourinary Musculoskeletal Endocrine Neurological Immunological Psychological Allergic Other			No No No No No No No No NA
086	F-NS	Skin EENT Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal Endocrine Neurological Immunological Psychological Allergic Other	1995 AUG-1996	C R	Eczema bilateral calves Wisdom teeth removed No No No No No No No No No No No NA
087	F-NS	Skin EENT Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal Endocrine	1968 1976 1987 1987 1996	R C R R R	No Tonsillectomy and adenoidectomy Presbyopia No No No No No Benign fibrous uterine tumor removal Partial hysterectomy Right knee injury - orthoscopic repair No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630391

Listing 16.3-37
Medical History by Subject
(Page 40 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
087	F-NS	Neurological Immunological Psychological Allergic Other	1952	C	No No No Allergic to penicillin NA
088	F-NS	Skin EENT Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal Endocrine Neurological Immunological Psychological Allergic Other	AUG-1992 1978 1990 1995	R C R R	No Wisdom teeth extracted Astigmatism bilateral eyes No No No No No Urinary tract infection Kidney infection No No No No No No NA
089	F-NS	Skin EENT Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal Endocrine Neurological Immunological Psychological	1980 1973 1970	C C R	Facial acne Myopia Frequent sore throats - tonsillectomy No No No No No No No No No No No No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630392

Listing 16.5-37
Medical History by Subject
(Page 41 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
089	F-NS	Allergic	1979	C	Allergic to mold
		Other	1979	C	Mild hay fever in summer NA
090	F-NS	Skin EENT	1995	C	No
			1944	R	Meniere's syndrome
			1996	R	T & A
			1996	R	Retina peel
		Breasts	1996	R	Removal of left eye due to cataract
			1983	C	Fibrocystic breasts
			1983	R	Two biopsies on right breast
					No
		Respiratory			No
		Cardiovascular	1961	C	Irregular heartbeat
		Lymphatic/Hematologic			No
		Gastrointestinal	1986	R	Laparoscopic cholecystectomy
			1990	C	Hiatal hernia
		Genitourinary	1985	R	Total hysterectomy
		Musculoskeletal	Unknown	C	General arthritis
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic	1940	C	Allergies - sulfa, prednisone
			1970	C	Seasonal allergies
		Other			NA
091	F-NS	Skin EENT Breasts Respiratory	1960	R	No
					Tonsillectomy
					No
					No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal	1942	R	Appendicitis/appendectomy
			1997	R	Hemorrhoids/hemorrhoidectomy
			1958	R	Tubal pregnancy
		Genitourinary	1977	R	Hysterectomy
		Musculoskeletal	1998	R	Left ankle fracture
			1991	C	Arthritic joints, both hands

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630393

Listing 16.5-37
Medical History by Subject
(Page 42 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
091	F-NS	Musculoskeletal	1999	R	Left foot hammer toes repair
			1998	R	Right foot hammer toes repair
		Endocrine	1952	R	Benign thyroid nodule removal
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic	1963	C	Nickel allergy
092	F-NS	Other			NA
		Skin			No
		EENT			No
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No
		Musculoskeletal			No
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
093	F-NS	Skin	1995	C	Acne
		EENT			No
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No
		Musculoskeletal			No
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.^b R=Resolved, C=Continuing.

PM3006630394

Listing 16.5-37
Medical History by Subject
(Page 43 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
093	F-NS	Allergic Other			No NA
094	F-NS	Skin EENT Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal Endocrine Neurological Immunological Psychological Allergic Other	1992 1983	C C	No Myopia No No No No No No No No No No No Allergy to cat hair NA
095	F-NS	Skin EENT Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal Endocrine Neurological Immunological Psychological Allergic Other	 1950	 R	No No No No No No Appendectomy No No No No No No No NA
096	F-NS	Skin EENT Breasts	1990	R	No Wisdom teeth extracted No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630395

Listing 16.5-37
Medical History by Subject
(Page 44 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
096	F-NS	Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary	1991	R	Miscarriage
		Musculoskeletal	1986	R	Fractured left ankle
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
097	F-NS	Skin			No
		EENT	1981	R	Wisdom teeth extracted
			1969	C	Myopia
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary	1986	R	Abnormal pap smear
			1992	R	Cesarean section
		Musculoskeletal			No
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
098	F-NS	Skin			No
		EENT	1975	R	Wisdom teeth extracted
			FEB-2001	C	Presbyopia
		Breasts	1996	C	Fibrocystic breast disease
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630396

Listing 16.5-37
Medical History by Subject
(Page 45 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
098	F-NS	Gastrointestinal	1991	R	No
		Genitourinary		R	Tubal ligation
			1991		Cesarean section
		Musculoskeletal			No
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
099	F-NS	Allergic			No
		Other			NA
		Skin	01-MAR-2001	C	Acne
		EENT	1990	C	Myopia
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No
		Musculoskeletal			No
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
100	F-NS	Allergic	1974	C	Allergy to penicillin
		Other			NA
		Skin	04-JUL-2000	R	Small ulcer on right thumb
		EENT	Unknown	R	Frequent ear infections
			1987	R	Wisdom teeth extracted
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary	1996	R	Tubular pregnancy
			1992	R	Miscarriage
		Musculoskeletal			No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630397

Listing 16.5-37
Medical History by Subject
(Page 46 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
100	F-NS	Endocrine Neurological Immunological Psychological Allergic Other			No No No No No NA
101	F-NS	Skin EENT Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal Endocrine Neurological Immunological Psychological Allergic Other	1990	R	Facial acne No No No No No No No No No No No No No No NA
102	F-NS	Skin EENT Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal Endocrine Neurological Immunological Psychological Allergic	1987 JUN-2000 1978 1980	 R R R	No Crowded mouth No No No No No Difficult labor with large baby Fractured left arm Fractured left arm No No No No No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630398

Listing 16.5-37
Medical History by Subject
(Page 47 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
102	F-NS	Other			NA
103	F-NS	Skin			No
		EENT	1987	C	Myopia
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No
		Musculoskeletal			No
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic	1980	C	Allergies - hayfever in summer
		Other			NA
104	M-NS	Skin			No
		EENT	1981	R	Frequent sore throat
			APR-2000	C	Myopia
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary	1991	R	Elective surgery - circumcision
		Musculoskeletal			No
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
105	M-NS	Skin			No
		EENT	1997	R	Impacted wisdom teeth
		Breasts			No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630399

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-37
Medical History by Subject
(Page 48 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
105	M-NS	Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal Endocrine Neurological Immunological Psychological Allergic Other	1991	R	No No No No No Left clavicle fracture No No No No No No NA
106	M-NS	Skin EENT Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal Endocrine Neurological Immunological Psychological Allergic Other	1994	R	No Wisdom teeth removal No No No No No No No No No No No No No NA
107	M-NS	Skin EENT Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal	1999 1984	C R	Lipoma left side of abdomen Tonsillectomy No No No No No No No No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.^b R=Resolved, C=Continuing.

PM3006630400

Listing 16.5-37
Medical History by Subject
(Page 49 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
107	M-NS	Endocrine Neurological Immunological Psychological Allergic Other	1998	R	No Brief loss of consciousness - x 4 over a couple years No No No NA
108	M-NS	Skin EENT Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal Endocrine Neurological Immunological Psychological Allergic Other	1998 1990 1980 1990 1990 1996 1987 1970	R R R R R R R C	Lipoma right arm Laceration to forehead Oral surgery - corrective Reconstructive surgery - oral No No No No No No Maxillar Fx - lost teeth Toe, small left foot Fx Left flank - rib Fx No Reduction in sense of smell No No No NA
109	M-NS	Skin EENT Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal Endocrine Neurological	 2000	 R	No No No No No No No Vasectomy No No No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630401

Listing 16.5-37
Medical History by Subject
(Page 50 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
109	M-NS	Immunological Psychological Allergic Other			No No No NA
110	M-NS	Skin EENT Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal Endocrine Neurological Immunological Psychological Allergic Other	1976 1995 1968 FEB-2000 OCT-1995 18-APR-2000 DEC-2000 1968	R C R R R C C	Laceration left knee Presbyopia Tonsillitis - T & A No No No Hematoma right leg No Left flank pain - kidney stone OCC RBCs in urine No Hypercholesterolemia No No No Allergy to PCN NA
111	M-NS	Skin EENT Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal Endocrine Neurological Immunological Psychological Allergic Other	1977 1987 1973	C R R	Eczema Impacted wisdom teeth x 4 No No No No No No No No No No No Allergic rxn to bee sting NA

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.^b R=Resolved, C=Continuing.

PM3006630402

Listing 16.5-37
Medical History by Subject
(Page 51 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
112	M-NS	Skin			No
		EENT	1955	C	Myopia
			FEB-2001	R	Dizziness inner ear vertigo
		Breasts			No
		Respiratory			No
		Cardiovascular	02-DEC-2000	C	Hypertension
		Lymphatic/Hematologic			No
		Gastrointestinal	1980	C	Hemorrhoids
		Genitourinary	1960	R	Right inguinal hernia - congenital
		Musculoskeletal			No
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
113	M-NS	Allergic			No
		Other			NA
		Skin			No
		EENT			No
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No
		Musculoskeletal	1960	R	Fx small finger left hand
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
114	M-NS	Allergic	1969	C	PCN allergy
		Other			NA
		Skin	1968	R	Laceration lower chin
			AUG-2000	R	Burn from iron left arm
		EENT	1998	R	Impacted wisdom teeth
			1976	C	Myopia
		Breasts			No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.^b R=Resolved, C=Continuing.

PM3006630403

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-37
Medical History by Subject
(Page 52 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
114	M-NS	Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal	NOV-1999	R	High bilirubin level
			1974	R	Appendicitis
		Genitourinary	1974	R	Inguinal hernia left side
		Musculoskeletal			No
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
115	M-NS	Skin			No
		EENT	1969	C	Presbyopia
			1969	R	Frequent sore throats
			1997	R	Impacted wisdom tooth
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No
		Musculoskeletal			No
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic	1970	R	Anaphylactic rxn bee sting
			1970	R	Allergy to trees and weeds
		Other			NA
116	M-NS	Skin			No
		EENT			No
		Breasts			No
		Respiratory			No
		Cardiovascular			No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630404

Listing 16.5-37
Medical History by Subject
(Page 53 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
116	M-NS	Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No
		Musculoskeletal	1993	R	Fx collarbone
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic	1983	C	Allergy to hay
		Other			NA
117	M-NS	Skin	1975	R	Cyst left wrist
			20-MAR-2001	C	Athletes foot
		EENT	1970	C	Myopia
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal	1994	R	Acid reflux
			1998	C	Heart burn
		Genitourinary	1991	R	Inguinal hernia
		Musculoskeletal	1997	C	Shoulder pain left
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
118	M-NS	Skin			No
		EENT	1997	C	Astigmatism both eyes
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No
		Musculoskeletal	1980	R	Torn ligaments right ankle

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.^b R=Resolved, C=Continuing.

PM3006630405

Listing 16.5-37
Medical History by Subject
(Page 54 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
118	M-NS	Musculoskeletal	1990	R	2 herniated discs
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
119	M-NS	Skin			No
		EENT			No
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No
		Musculoskeletal	1994	R	Fractured right leg- femur, fibula, tibia and humerus
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic	1985	C	Allergy to cats
		Other			NA
120	M-NS	Skin			No
		EENT			No
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary	1999	R	Vasectomy
		Musculoskeletal	1971	R	Fractured left collar bone
			1978	R	Fractured right collar bone
			1984	R	Fractured right wrist
			1982	R	Fractured right ankle
			1996	R	Separated left shoulder
		Endocrine			No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630406

Listing 16.5-37
Medical History by Subject
(Page 55 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
120	M-NS	Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
121	M-NS	Skin			No
		EENT			No
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No
		Musculoskeletal			No
		Endocrine			No
		Neurological	1978	C	Sinus headache
		Immunological			No
		Psychological	1999	C	Anxiety disorder
		Allergic	1998	C	Allergic to ragweed, mildew and tree pollen
		Other			NA
122	M-NS	Skin	1987	R	Laceration left hand
			1986	R	Laceration head
		EENT			No
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No
		Musculoskeletal			No
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.^b R=Resolved, C=Continuing.

Listing 16.5-37
Medical History by Subject
(Page 56 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
123	M-NS	Skin	1993 1999 1971 1974 1993 1992	C C R R R R	No
					Presbyopia
					Myopia
					Hearing loss - stapedectomy right
					Hearing loss - stapedectomy left
					Left, lower wisdom tooth - impacted; extracted
					Deviated septum - surgically corrected
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary	1970	R	Vasectomy
		Musculoskeletal	1982	R	Fractured 5th phalange - no treatment
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
124	M-NS	Skin	1995 1997 1987 1997 1995	R R R R C	Ingrown toenails bilateral
					Multiple lacerations bilateral hands
					Laceration left cheek
					4 wisdom teeth removed
					Myopia
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary	17-MAY-2000	C	Right inguinal hernia
		Musculoskeletal			No
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic	1987	R	Seasonal allergies

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630408

Listing 16.5-37
Medical History by Subject
(Page 57 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
124	M-NS	Other			NA
125	M-NS	Skin			No
		EENT	1989	C	Myopia - contacts
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal	1990	R	Appendicitis appendectomy
		Genitourinary			No
		Musculoskeletal	JAN-1997	R	Fracture facial bones secondary to motor vehicle accident
			JAN-1997	R	Fracture left collarbone secondary to motor vehicle accident
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic	1982	C	Penicillin allergy
		Other			NA
126	M-NS	Skin			No
		EENT	1996	R	Cataracts, both eyes, removal and lens placement
			Unknown	R	Tonsillectomy and adenoidectomy
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary	1970	R	Left inguinal hernia repair
			1972	R	Vasectomy
		Musculoskeletal	1992	C	Carpal tunnel right hand
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
127	M-NS	Skin			No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.^b R=Resolved, C=Continuing.

Listing 16.5-37
Medical History by Subject
(Page 58 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
127	M-NS	EENT	1996	R	Impacted wisdom teeth removed
			1988	C	Myopia
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary	1982	R	Abnormal function of valve between right ureter and right kidney - surgical repair
			09-FEB-2001	R	Vasectomy
		Musculoskeletal			No
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
128	M-NS	Skin			No
		EENT	1963	C	Presbyopia
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No
		Musculoskeletal	1984	R	Fx, right small finger
			1968	R	Fx, left wrist
			1972	R	Fx, left lower leg
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic	Unknown	C	Allergy to cats
		Other			NA
129	M-NS	Skin			No
		EENT	1975	R	Ear infections - tube placement
		Breasts			No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630410

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-37
Medical History by Subject
(Page 59 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
129	M-NS	Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No
		Musculoskeletal			No
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
130	M-NS	Skin	1986	R	Laceration to midback from fall
		EENT			No
		Breasts			No
		Respiratory			No
		Cardiovascular	1970	R	No
		Lymphatic/Hematologic			No
		Gastrointestinal			Rectal bleeding from kick to stomach
		Genitourinary			No
		Musculoskeletal			No
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
131	M-NS	Skin			No
		EENT			No
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary	1998	R	Right inguinal hernia
			1995	R	Elective vasectomy

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.^b R=Resolved, C=Continuing.

PM3006630411

Listing 16.5-37
Medical History by Subject
(Page 60 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
131	M-NS	Musculoskeletal	1977	R	Left arm fracture
			1988	R	Left wrist fracture
			1982	R	Right foot fracture
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
Other			NA		
132	M-NS	Skin	OCT-1994	R	Deep abrasion left shoulder
			OCT-1994	R	Laceration forehead
			1998	R	Laceration right forearm
			19-MAY-2000	R	Laceration left arm
			17-OCT-1999	R	Foreign body in right eye
		EENT	1992	C	Myopia
			10-NOV-1975	R	Congenital esophagus narrowing
					No
					No
					No
		Breasts			No
					No
					No
					No
					No
		Respiratory			No
					No
					No
					No
					No
		Cardiovascular			No
					No
					No
			No		
			No		
Lymphatic/Hematologic			No		
			No		
			No		
			No		
			No		
Gastrointestinal			No		
			No		
			No		
			No		
			No		
Genitourinary			No		
			No		
			No		
			No		
			No		
Musculoskeletal	JUL-1996	R	Fractured nose		
	FEB-1997	R	Fractured nose		
	JUN-1997	R	Fractured nose		
	FEB-1997	R	Fractured ribs right side		
			No		
Endocrine			No		
			No		
			No		
			No		
			No		
Neurological			No		
			No		
			No		
			No		
			No		
Immunological			No		
			No		
			No		
			No		
			No		
Psychological	1995	R	Counseling due to ending relationship		
	1978	C	Allergic to parmesan cheese		
			NA		
			NA		
			NA		
Allergic			NA		
			NA		
			NA		
			NA		
			NA		
Other			NA		
			NA		
			NA		
			NA		
			NA		
Breasts			No		
			No		
			No		
			No		
			No		
EENT	1992	C	Myopia		
	1973	R	Frequent sore throats		
			No		
			No		
			No		
Skin			No		
			No		
			No		
			No		
			No		

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630412

Listing 16.5-37
Medical History by Subject
(Page 61 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
133	M-NS	Respiratory	1999	R	No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No
		Musculoskeletal			Herniated disc
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			Allergic to cockroaches
134	M-NS	Other	1999	C	NA
		Skin			No
		EENT			Myopia
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			No
		Musculoskeletal			No
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			Allergy to penicillin
		Other			NA
135	M-NS	Skin	APR-2000	R	No
		EENT			Wisdom teeth extraction
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary			Right side inguinal hernia repair
		Musculoskeletal			No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630413

Listing 16.5-37
Medical History by Subject
(Page 62 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
135	M-NS	Endocrine Neurological Immunological Psychological Allergic Other			No No No No No NA
500	F-NS	Skin EENT Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal Endocrine Neurological Immunological Psychological Allergic Other	1992 1990 1975 1997 1992 1993	R C C C R R	No Four impacted wisdom teeth Myopia No No Slight heart murmur No Gallstones No Left knee cartilage tear Left knee anterior cruciate ligament repair No No No No No NA
501	F-NS	Skin EENT Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal Endocrine Neurological Immunological	1980 1974 FEB-2001	C R R	No Myopia Elective surgery - tonsillectomy & adenoidectomy Abnormal mammogram No No No No No No No No No No

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

PM3006630414

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-37
Medical History by Subject
(Page 63 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
501	F-NS	Psychological Allergic Other			No No NA
502	F-S	Skin EENT Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal Endocrine Neurological Immunological Psychological Allergic Other	1983 1980's 1986 SEP-1999 1980's	R C R C R	No Overcrowding in mouth Myopia No No No No Appendicitis Irregular menstrual cycles Hairline fracture - little toe left foot No No No No No No NA
503	F-S	Skin EENT Breasts Respiratory Cardiovascular Lymphatic/Hematologic Gastrointestinal Genitourinary Musculoskeletal Endocrine Neurological Immunological Psychological Allergic Other			No No No No No No No No No No No No No No No NA
504	F-S	Skin	1977	R	Urticaria

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.^b R=Resolved, C=Continuing.

PM3006630415

Listing 16.5-37
Medical History by Subject
(Page 64 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
504	F-S	Skin	APR-2001	C	Toenail fungus
		EENT	1964	R	Frequent sore throats
			1958	C	Myopia
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary	1990	R	Elective sterilization
		Musculoskeletal	1981	R	Fracture of facial bone
			JUL-1995	R	Fracture of ribs
			1977	R	Fracture of right arm
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA
505	F-NS	Skin			No
		EENT	1970	C	Presbyopia
			1954	R	Sore throats tonsillectomy & adenoidectomy
		Breasts			No
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic			No
		Gastrointestinal			No
		Genitourinary	1962	R	Tubal ligation
			1993	R	Abnormal pap smear
		Musculoskeletal	FEB-1993	R	Surgery for left - hand carpal tunnel syndrome
			MAR-1993	R	Surgery for right - hand carpal tunnel syndrome
			DEC-1993	R	Right - hand surgical tendon release
		Endocrine			No
		Neurological			No
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.^b R=Resolved, C=Continuing.

Listing 16.5-37
Medical History by Subject
(Page 65 of 65)

Subject Number	Subject Classification ^a	System	Date of Onset	Status ^b	Diagnosis and/or Procedure
506	F-S	Skin	24-APR-2001	R	Removal of benign sebaceous cyst under right eye
		EENT	1978	C	Myopia
			FEB-2001	C	Right lower wisdom tooth pain
		Breasts	APR-2000	C	Fibrocystic disease, no Tx recommended
		Respiratory			No
		Cardiovascular			No
		Lymphatic/Hematologic	1987	R	Anemia secondary to diet, Tx with diet
		Gastrointestinal			No
		Genitourinary	MAY-1993	R	C section X 2 (01/1997 & 05/1993)
		Musculoskeletal			No
		Endocrine			No
		Neurological	1972	R	Concussion secondary to fall, no sequelae
			JAN-1999	C	Migraines, frequency approximately 1/year
		Immunological			No
		Psychological			No
		Allergic			No
		Other			NA

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b R=Resolved, C=Continuing.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-19
Vital Signs by Subject
(Page 20 of 27)

Subject Number	Subject Classification ^a	Timepoint	Blood Pressure		Pulse (beats/min)	Respiration (breaths/min)	Oral Temperature (°C)
			Systolic (mmHg)	Diastolic (mmHg)			
102	F-NS	Screening Enrollment	112	67	70	12	36.6
		Week 1	107	63	78	16	36.1
		Week 2	113	76	103	16	36.3
		Week 3	106	61	70	12	36.9
		Week 6	123	67	67	16	36.8
103	F-NS	Screening Enrollment	134	75	79	16	36.3
		Week 1	113	78	79	16	36.5
		Week 2	121	67	75	16	36.1
		Week 3	115	70	73	16	37.5
		Week 6	122	60	68	16	36.6
104	M-NS	Screening Enrollment	121	71	82	20	36.5
		Week 1	100	61	58	12	36.5
		Week 2	112	65	59	12	36.3
		Week 3	115	64	54	12	36.8
		Week 6	106	61	63	16	36.6
105	M-NS	Screening Enrollment	111	61	62	16	36.2
		Week 1	115	62	64	16	36.4
		Week 2	128	81	53	12	36.2
		Week 3	122	80	50	16	36.2
		Week 6	136	77	58	12	36.2
106	M-NS	Screening Enrollment	143	79	64	16	36.2
		Week 1	126	70	51	16	36.0
		Week 2	144	88	67	12	35.7
		Week 3	144	75	49	12	36.2
		Week 6	109	61	44	12	35.9
		Screening Enrollment	113	68	42	16	35.9
		Week 1	122	70	58	12	36.6
		Week 2	112	65	41	16	36.8
		Week 3	113	69	39	16	36.2
		Week 6	113	69	39	16	36.2

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Draft 1: 24 July 2002

Page 14722 of 15132

PM3006630077

Listing 16.5-38
Concomitant Medications by Subject
(Page 2 of 17)

Subject Number	Subject Classification ^a	Any Medications Taken?	Drug	Indication	Dose	Route	Frequency	Start Date	Stop Date
008	F-S	Yes	Calcium Plus	Health	2 caps	po	bid	1999	ONGOING
			Mineral Blast	Health	1 cap	po	qod	1999	ONGOING
			Multitech formula	Health	1 cap	po	qod	1999	ONGOING
			Vitamin C formula	Health	1 cap	po	qd	1999	ONGOING
			Ultimate Aloe	Health	1 cap	po	pm	1999	ONGOING
			Oxygen Plus	Health	1 tab	po	2-3x mo	1999	ONGOING
			Ginger	Health	500 mg	po	bid	FEB-2001	12-APR-2001
			Astragalus	Health	250 mg	po	qd	FEB-2001	12-APR-2001
			Milk thistle	Health	400 mg	po	bid	FEB-2001	12-APR-2001
			Licorice	Health	500 mg	po	bid	FEB-2001	12-APR-2001
			Acetaminophen	HA	500 mg	po	pm	APR-2000	ONGOING
			Cataflam	HA	50 mg	po	pm	1999	ONGOING
			Ibuprofen	HA	200 mg	po	pm	1999	ONGOING
			Depo-provera	To stop period	Unknown	im	x1	19-MAR-2001	19-MAR-2001
			Pseudoephedrine	Allergies	60 mg	po	pm	27-APR-2001	29-APR-2001
			Doxycycline	Pelvic infection	200 mg	po	qd	15-MAR-2001	25-MAR-2001
			Metronidazole	Pelvic infection	1000 mg	po	qd	15-MAR-2001	25-MAR-2001
			Zithromax	Pelvic infection	500 mg	po	qd	15-MAR-2001	17-MAR-2001
			Metronidazole	Pelvic infection	500 mg	po	qd	12-FEB-2001	14-FEB-2001
			Lorabid	Pelvic infection	400 mg	po	qd	12-FEB-2001	22-FEB-2001
			Zithromax	Pelvic infection	500 mg	po	qd	12-FEB-2001	14-FEB-2001
			Flonase	Allergies	2 squirts	in	qd	15-MAY-2001	ONGOING
			Allegra	Allergies	180 mg	po	qd	15-MAY-2001	ONGOING
			Tylenol #3	OS injury	1 tab	po	qhs	08-JUN-2001	11-JUN-2001
			Unknown medication	OS injury	1 drop	oph	qid	08-JUN-2001	11-JUN-2001
009	F-S	Yes	Vitamin E	Health	800 iu	po	qd	1997	ONGOING
			Selenium	Health	1x 200 mcg	po	qd	1997	ONGOING
			Vitamin A	Health	1x 25000 iu	po	qd	1997	ONGOING
			Siberian ginseng root	Health	1x 0.41 g	po	qd	1998	ONGOING
			Centrum Silver multi-vitamin and multi-mineral	Health	1 tab	po	qd	1970	ONGOING
			Bilberry extract	Health	1x 125 mg	po	qd	1999	ONGOING
			Folic Acid	Health	1x 800 mcg	po	3 per week	1999	ONGOING
			Vitamin C	Health	1x 500 mg	po	3 per week	1997	ONGOING
			Calcium, Magnesium, Zinc	Health	1 tab	po	3 times per week	1975	ONGOING

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-38
Concomitant Medications by Subject
(Page 3 of 17)

Subject Number	Subject Classification ^a	Any Medications Taken?	Drug	Indication	Dose	Route	Frequency	Start Date	Stop Date
009	F-S	Yes	Aleve	Generalized aches and pain	Unknown	po	prn	1996	ONGOING
010	F-S	Yes	Ibuprofen	Headache	200 mg	po	prn	12-JAN-2001	12-MAR-2001
011	F-S	No							
012	F-S	Yes	Veetids	Tooth infection	500 mg	po	qid	19-MAR-2001	28-MAR-2001
			Tylenol with codeine #3	Pain due to tooth infection	1 tab	po	3 doses	20-MAR-2001	21-MAR-2001
			Pamprin	Menstrual cramps	2 tabs	po	prn	1999	11-APR-2001
			Acetaminophen	Tooth infection pain	1000 mg	po	prn	10-APR-2001	11-APR-2001
			Acetaminophen	General aches/headache	1000 mg	po	prn	1987	ONGOING
			Tylenol Cold	URI	2 tabs	po	bid	25-APR-2001	29-APR-2001
			Antacid/Equate	Prophylaxis	2 tabs	po	once	28-APR-2001	28-APR-2001
			Aspirin	URI	486 mg	po	once	25-APR-2001	25-APR-2001
			Nyquil	URI	Unknown	po	qd	26-APR-2001	27-APR-2001
013	F-S	Yes	Excedrin migraine	Headache	2 tabs	po	prn	12-JAN-2001	06-APR-2001
			Ibuprofen	Headache	2 tabs	po	prn	12-JAN-2001	08-APR-2001
014	F-S	Yes	Ambien	Insomnia	5 mg	po	qhs	JAN-2001	JAN-2001
			Roxicet	Torn ligament	1 tab	po	once	01-MAR-2001	01-MAR-2001
			Darvocet	Torn ligament	1 tab	po	prn	02-MAR-2001	03-MAR-2001
			Ibuprofen	Torn ligament	200 mg	po	prn	04-MAR-2001	14-MAR-2001
			Trazodone	Insomnia	50 mg	po	prn	APR-2001	ONGOING
			Ibuprofen	Generalized aches and pains	200 mg	po	qd	1991	ONGOING
			Zyrtec	Allergies	5 mg	po	qd	MAR-2000	31-MAR-2001
			Allegra	Allergies	60 mg	po	qd	MAY-1999	MAR-2000
			Darvocet	Muscle aches	1 tab	po	prn	25-APR-2001	25-APR-2001
			Pepto-Bismal	Indigestion	NA	po	prn	15-MAY-2001	15-MAY-2001
			Zyrtec	Allergies	5 mg	po	prn	06-JUN-2001	07-JUN-2001
			Sinutab	Allergies	1 tab	po	qd	10-JUN-2001	10-JUN-2001
			Benedryl	Allergies	25 mg	po	qd	09-JUN-2001	09-JUN-2001
			Darvocet-n-100	General aches & pains	1 tab	po	prn	08-JUN-2001	ONGOING
			Lorazepam	Insomnia	0.5 mg	po	prn	10-JUN-2001	ONGOING
015	F-S	Yes	Ibuprofen	Headache	200 mg	po	once	02-MAR-2001	02-MAR-2001

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-38
Concomitant Medications by Subject
(Page 4 of 17)

Subject Number	Subject Classification ^a	Any Medications Taken?	Drug	Indication	Dose	Route	Frequency	Start Date	Stop Date
015	F-S	Yes	Thera flu	Cold symptoms	1 cap	po	prn	02-MAR-2001	04-MAR-2001
			Acetaminophen	Tooth ache	650 mg	po	prn	06-MAY-2001	06-MAY-2001
			Amoxicillin	Tooth extraction	500 mg	po	qid	10-MAY-2001	17-MAY-2001
			Vicodin	Tooth extraction	1 tab	po	q6hr	10-MAY-2001	12-MAY-2001
016	F-S	Yes	Vitamin B6	Health	1x 200 mg	po	qd	SEP-2000	ONGOING
			Ibuprofen	Headaches, other aches & pains	400 mg	po	4x	20-JAN-2001	04-APR-2001
			Differin cream, 0.1%	Acne	Unknown	top	prn	1998	ONGOING
017	F-S	Yes	Aspirin	HA	325 mg	po	prn	08-APR-2001	08-APR-2001
018	F-S	Yes	Milk thistle	Psoriasis	280 mg	po	qd	10-APR-2001	11-APR-2001
			Multivitamin	General health	1 tab	po	qd	NOV-2000	ONGOING
			Vitamin E	Skin	400 iu	po	qd	NOV-2000	ONGOING
			Ery-Tab	URI	250 mg	po	bid	07-JUN-2001	ONGOING
019	F-S	Yes	Multivitamin	Health	1 tab	po	qd	1998	ONGOING
020	F-S	Yes	Excedrin	HA	1 tab	po	prn	MAR-2001	ONGOING
			Excedrin PM	Sleeplessness	1 tab	po	prn	MAR-2001	ONGOING
			Tylenol Cold	URI	1 tab	po	bid	03-JUN-2001	03-JUN-2001
021	F-S	Yes	Tri-Levlen	Oral contraceptive	1 tab	po	qd	01-JAN-2001	ONGOING
			Aleve	Muscle aches	2 tabs	po	prn	10-MAY-2001	10-MAY-2001
022	F-S	Yes	Aleve	Menstrual cramps	3 tabs	po	3x	16-APR-2001	16-APR-2001
			Zyrtec	Nasal congestion	5 mg	po	prn	09-MAY-2001	11-MAY-2001
			Nasa Cort	Nasal congestion	2 squirts	in	prn	09-MAY-2001	11-MAY-2001
023	F-S	No							
024	F-S	Yes	Motrin	Knee pain	400 mg	po	bid	20-MAR-2001	20-MAR-2001
			Glucosamine HCL	Health	500 mg	po	qod	JAN-2000	ONGOING
			Mela-cal	Health	1 tab	po	qod	JAN-2000	ONGOING
025	F-S	Yes	Maximin	Health	1 tab	po	qd	APR-1999	ONGOING

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630421

Listing 16.5-38
Concomitant Medications by Subject
(Page 5 of 17)

Subject Number	Subject Classification ^a	Any Medications Taken?	Drug	Indication	Dose	Route	Frequency	Start Date	Stop Date
025	F-S	Yes	Lidocaine	Wrist strain	Unknown	im	1x	07-MAY-2001	07-MAY-2001
			Cortisone	Wrist strain	Unknown	im	1x	07-MAY-2001	07-MAY-2001
026	F-S	Yes	Xenadrine	Wt. loss	2 tabs	po	qd	2001	ONGOING
			Trazadone	Depression	100 mg	po	qd	1996	ONGOING
			Equate Nighttime	Sinus congestion	30 cc	po	x1	09-APR-2001	09-APR-2001
			Ibuprofen	Muscle pain	800 mg	po	prn	Unknown	ONGOING
			Sudafed	Sinus congestion	120 mg	po	x1	08-APR-2001	08-APR-2001
			B-Complex	Health	1 cap	po	qd	FEB-2001	ONGOING
			Nr-Jizer	Energy	1 tab	po	qd	2000	12-APR-2001
			Ultra Mega	Health	2 tabs	po	qd	29-APR-2001	ONGOING
			Suphedrine	Sinus congestion	60 mg	po	x2	28-APR-2001	29-APR-2001
			Wal-Finate	Sinus congestion	2 tabs	po	x2	28-APR-2001	29-APR-2001
			Zithromax	Sinus infection	250 mg	po	bid	08-MAY-2001	11-MAY-2001
			Herbalife Ultimate Green Plan	Health	11 tabs	po	qd	21-MAY-2001	ONGOING
027	F-S	Yes	Alka Seltzer	Headache, upset stomach	2 tabs	po	qd	1999	ONGOING
			Tylenol PM	Sleeplessness	1 cap	po	once	07-APR-2001	07-APR-2001
			Sudafed	Cold symptoms	30 mg	po	bid	09-APR-2001	09-APR-2001
			Sudafed	Cold symptoms	30 mg	po	tid	10-APR-2001	12-APR-2001
028	F-S	Yes	St. Johns Wort	Mood enhancer	300 mg	po	prn	DEC-2000	ONGOING
			PMS herbal formula	Pre-menstrual symptoms	1 tab	po	prn	FEB-2001	ONGOING
			B-12 dots	Health	500 mcg	po	prn	APR-2000	ONGOING
			Ortho-cyclen	Oral contraceptive	1 tab	po	qd	1996	ONGOING
029	F-S	Yes	Nelon 1/35 - 28	Birth control	1 tab	po	qd	1997	ONGOING
030	F-S	Yes	Macroclantin	UTI	100 mg	po	bid	08-APR-2001	15-APR-2001
			Acetaminophen	HA	500 mg	po	once	12-APR-2001	12-APR-2001
031	F-S	Yes	Ortho Tri-cyclen	Birth control	1 tab	po	qd	1999	ONGOING
032	F-S	Yes	Zoloft	Postpartum depression	100 mg	po	qd	NOV-2001	12-JUN-2001
			Depo-Provera	Contraception	Unknown	im	q 3mo	AUG-1998	ONGOING

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-38
Concomitant Medications by Subject
(Page 6 of 17)

Subject Number	Subject Classification ^a	Any Medications Taken?	Drug	Indication	Dose	Route	Frequency	Start Date	Stop Date
032	F-S	Yes	Multivitamin	Supplement	1 tab	po	qd	JAN-2001	ONGOING
			Tylenol	Sore shoulder/arm	500 mg	po	3x	10-MAY-2001	11-MAY-2001
			Zoloft	Postpartum depression	150 mg	po	qd	13-JUN-2001	ONGOING
033	F-S	Yes	Loestrin	Contraception	1.5 mg	po	qd	1999	ONGOING
			Albuterol	Viral bronchitis	2 puffs	inh	qd prn	08-JUN-2001	ONGOING
			Doxycycline	Viral bronchitis	100 mg	po	bid	11-JUN-2001	ONGOING
			Promethazine	Viral bronchitis	2 tsp	po	prn	29-MAY-2001	04-JUN-2001
034	F-S	Yes	Paxil	Depression	30 mg	po	qd	APR-1999	15-MAY-2001
			Claritin	Allergy symptoms	100 mg	po	qd	15-JAN-2001	ONGOING
			Effexor	Depression	75 mg	po	qd	15-MAY-2001	ONGOING
035	F-S	Yes	Estradiol transdermal system	Menopausal symptoms	.1 mg	trans	Unknown	AUG-2000	ONGOING
			Nystatin	Fungus on tongue	500000 u	po	7x	08-APR-2001	15-APR-2001
			Vitamin B6	Health	50 mg	po	qd	APR-2000	ONGOING
			Ultra lipotropic fat metabolizer	Health	Unknown	po	qd	DEC-2000	ONGOING
			Heart Right multivitamin	Health	Unknown	po	qd	21-APR-2001	ONGOING
			Calcet	Health	Unknown	po	qd	APR-2000	ONGOING
			Vitamin E	Health	400 IU	po	qd	APR-2000	ONGOING
			Vitamin C	Health	1000 mg	po	qd	APR-2000	ONGOING
			Nuprin	Stiff neck	400 mg	po	1x	11-JUN-2001	11-JUN-2001
036	M-S	Yes	Ibuprofen	Headache	400 mg	po	prn	2000	08-APR-2001
			Vitamin C	Health	500 mg	po	qd	FEB-2000	ONGOING
			Multivitamin	Health	1 tab	po	qd	FEB-2000	ONGOING
			Vitamin E	Health	400 iu	po	qd	FEB-2000	ONGOING
037	M-S	Yes	Gentamicin	Pink eye (right eye)	3 mg	od	qid	20-MAR-2001	26-MAR-2001
			Halls Cough Drops	Viral illness	Unknown	po	once	27-APR-2001	27-APR-2001
038	M-S	No							
039	M-S	Yes	Propoxyphene	Back pain	2 tabs	po	tid	1999	01-MAR-2001
			Acetaminophen	Headache	650 mg	po	1x	15-APR-2001	15-APR-2001

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-38
Concomitant Medications by Subject
(Page 7 of 17)

Subject Number	Subject Classification ^a	Any Medications Taken?	Drug	Indication	Dose	Route	Frequency	Start Date	Stop Date
-039	M-S	Yes	Cerivastatin Sodium	Hypercholesterolemia	0.4 mg	po	qhs	18-MAY-2001	ONGOING
040	M-S	Yes	Aleve	Muscle ache	440 mg	po	bid	15-APR-2001	15-APR-2001
041	M-S	No							
042	M-S	Yes	Tylenol	HA	650 mg	po	1x	15-MAR-2001	15-MAR-2001
			Aleve	General aches	440 mg	po	1x	12-MAR-2001	12-MAR-2001
			Aleve	HA	440 mg	po	2x	16 MAY 2001	18-MAY 2001
043	M-S	Yes	Tylenol	HA	650 mg	po	3x	16-JAN-2001	04-APR-2001
044	M-S	Yes	Multivitamin	Health	1/2 tab	po	qd	1999	ONGOING
			Vitamin E	Health	800 iu	po	qd	1999	ONGOING
			Vitamin C	Health	2500 mg	po	qd	1999	ONGOING
045	M-S	No							
046	M-S	Yes	Cimetidine	Heartburn	200 mg	po	prn	1996	ONGOING
047	M-S	Yes	Risperdal	Bipolar disorder	1 mg	po	qd	01-MAR-2001	ONGOING
			Bupropion	Depression	150 mg	po	bid	2000	ONGOING
048	M-S	No							
049	M-S	Yes	Multivitamin	Health	1 tab	po	qd	1995	ONGOING
			Glucosamine Chondroitin	Health	1 tab	po	tid	1998	ONGOING
			ASA	Anti-thrombolytic	325 mg	po	qd	1999	ONGOING
			Zocor	Hypercholesterolemia	5 mg	po	qd	2000	ONGOING
			Vitamin E	Health	1000 IU	po	qd	1999	ONGOING
			Ginkoba	Health	1 tab	po	tid	1999	ONGOING
050	M-S	Yes	Ibuprofen	Muscle pain	400 mg	po	bid	19-MAR-2001	21-MAR-2001
			Erodolac	Epicondylitis	400 mg	po	tid	05-APR-2001	07-JUN-2001
051	M-S	No							

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

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Listing 16.3-38
Concomitant Medications by Subject
(Page 8 of 17)

Subject Number	Subject Classification ^a	Any Medications Taken?	Drug	Indication	Dose	Route	Frequency	Start Date	Stop Date
052	M-S	Yes	Multivitamin	Health	1 tab	po	1x wk	JAN-2000	ONGOING
			Ibuprofen	HA	400 mg	po	pm	01-APR-2001	01-APR-2001
			Ibuprofen	HA	200 mg	po	x1	24-MAY-2001	24-MAY-2001
053	M-S	Yes	Multivitamin	Health	1 tab	po	qd	FEB-2001	ONGOING
			Vitamin C	Health	2000 mg	po	qd	FEB-2001	ONGOING
			Tylenol	Left shoulder pain	1000 mg	po	qd	20-APR-2001	20-APR-2001
			Non-aspirin pain reliever	Left shoulder pain	650 mg	po	tid	22-APR-2001	22-APR-2001
054	M-S	Yes	Ibuprofen	HA	400 mg	po	1x	10-MAR-2001	10-MAR-2001
			Ibuprofen	HA	400 mg	po	1x	25-MAR-2001	25-MAR-2001
055	M-S	Yes	Tylenol 3	Left leg/ankle injury	2 tabs	po	once	21-APR-2001	21-APR-2001
			Ibuprofen	Left leg/ankle pain	400 mg	po	qd	JAN-2001	23-APR-2001
			Men's vitamins	Health	1 tab	po	qd	17-NOV-2000	ONGOING
056	M-S	No							
057	M-S	No							
058	M-S	Yes	Aspirin	Headache	325 mg	po	pm	19-APR-2001	ONGOING
059	M-S	Yes	Excedrin	HA	1-2 tabs	po	pm	1987	ONGOING
			Nyquil	Cold symptoms	2 tbsp	po	2 times	FEB-2001	FEB-2001
			Tylenol Cold	Cold symptoms	2 tabs	po	once	FEB-2001	FEB-2001
060	M-S	No							
061	M-S	Yes	Tylenol Sinus	Chest congestion and sinus congestion	1 tab	po	pm	21-MAY-2001	27-MAY-2001
062	M-S	Yes	Lithium	Bi-polar disorder	300 mg	po	bid	1995	ONGOING
			Zoloft	Bi-polar disorder	300 mg	po	qd	1995	ONGOING
063	M-S	Yes	Benadryl	Seasonal allergies	25 mg	po	pm	01-FEB-2001	ONGOING
065	M-S	Yes	Multiple vitamin	Health	1 tab	po	pm	NOV 2000	ONGOING

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-38
Concomitant Medications by Subject
(Page 9 of 17)

Subject Number	Subject Classification ^a	Any Medications Taken?	Drug	Indication	Dose	Route	Frequency	Start Date	Stop Date
065	M-S	Yes	Tylenol	Headache	650 mg	po	once	24-APR-2001	24-APR-2001
			Advil	Headache	400 mg	po	once	24-APR-2001	24-APR-2001
066	M-S	Yes	Vicodin	Tooth extraction	1 tab	po	prn	23-APR-2001	ONGOING
067	M-S	Yes	Dixaphedrine	Cold s/s	1 tab	po	1x	01-APR-2001	01-APR-2001
068	M-S	Yes	Ibuprofen	Puffed muscle in back	600 mg	po	tid	24-APR-2001	ONGOING
			Cyclobenzaprine	Pulled muscle in back	10 mg	po	13-14 doses	20-APR-2001	25-APR-2001
			Acetaminophen with codeine #3	Pulled muscle in back	1 tab	po	25 doses	17-APR-2001	19-APR-2001
			Acetaminophen with codeine #3	Abscessed tooth	2 tabs	po	q 6 hours	02-MAY-2001	07-MAY-2001
			Penicillin	Abscessed tooth	500 mg	po	qid	02-MAY-2001	07-MAY-2001
069	M-S	Yes	Ibuprofen	Mouth pain	400 mg	po	prn	01-APR-2001	05-APR-2001
			Acetaminophen	Mouth pain	200 mg	po	prn	15-MAR-2001	01-APR-2001
			Propoxyphene Napsylate	Mouth pain	1 tab	po	prn	29-MAR-2001	07-APR-2001
			Percocet	Mouth pain	2 tabs	po	prn	08-APR-2001	21-APR-2001
			Amoxicillin	Mouth infection	1 tab	po	qd x 10	15-MAR-2001	25-MAR-2001
			Ibuprofen	Mouth pain	200 mg	po	3 times	12-MAR-2001	14-MAR-2001
071	F-NS	Yes	Ibuprofen	Headache	400 mg	po	5x	1999	11-MAR-2001
			Multivitamin	Health	1 tab	po	prn	1999	ONGOING
			Nasal spray	Allergy sxs	1 spray	nasal	2 times per week	APR-2000	11-MAR-2001
			Aveda acne treatment	Facial acne	1 app	top	prn	OCT-2000	ONGOING
			Motrin	Menstrual cramps	2 tabs	po	prn	20-MAY-2001	ONGOING
072	F-NS	Yes	Ibuprofen	Headache	600 mg	po	once	23-MAR-2001	23-MAR-2001
			Ibuprofen	Headache	200 mg	po	once	04-APR-2001	04-APR-2001
			Zovirax	Cold sore	5 %	top	prn	01-JUN-2001	04-JUN-2001
			Sulfacetamide	Conjunctivitis	1 drop	od	tid	04-JUN-2001	07-JUN-2001
073	F-NS	No							
074	F-NS	Yes	Multivitamin	General health	1 tab	po	4 times per week	1998	ONGOING
			Xenadrine	Energy during work out	2 tabs	po	4 times per week	1999	APR-2001

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-38
Concomitant Medications by Subject
(Page 10 of 17)

Subject Number	Subject Classification ^a	Any Medications Taken?	Drug	Indication	Dose	Route	Frequency	Start Date	Stop Date
074	F-NS	Yes	Lo/Ovral Mircette	Oral contraceptive Oral contraceptive	1 pill 1 pill	po po	qhs qhs	1999 21-MAY-2001	20-MAY-2001 ONGOING
075	F-NS	Yes	Multivitamin	Health	1 tab	po	qd	09-MAY-2001	ONGOING
076	F-NS	Yes	Demulen Tylenol	Oral contraceptive Headache	1 tab 1000 mg	po po	qd 1xmo	1995 1992	ONGOING ONGOING
077	F-NS	Yes	Joint formula Adipex	Supplement Appetite suppressant	1 cap 18.75 mg	po po	x2 qd qd	MAR-2001 20-APR-2001	24-APR-2001 ONGOING
078	F-NS	No							
079	F-NS	No							
080	F-NS	Yes	Aspirin Vitamin E Calcium Caladryl Clear Aspirin	Aches and pains Skin sores Heartburn Rash Sore throat, diarrhea, and stomach queasiness	650 mg 200 iu 400 mg NA 650 mg	po top po top po	once once once pm pm	16-MAR-2001 28-MAR-2001 09-APR-2001 29-APR-2001 02-MAY-2001	16-MAR-2001 28-MAR-2001 09-APR-2001 30-APR-2001 13-MAY-2001
081	F-NS	Yes	Multivitamin Cod liver oil Natural B Aspirin Aleve	Health Health Health Health Headache	1 tab Unknown 1 tab 325 mg 440 mg	po po po po po	qd qd qd qd once	1998 2001 1999 1998 28-MAR-2001	ONGOING ONGOING ONGOING ONGOING 28-MAR-2001
082	F-NS	Yes	Aspirin	Headache	650 mg	po	once	15-APR-2001	15-APR-2001
083	F-NS	Yes	Neosporin	Cut on right 5th digit	NA	top	once	14-APR-2001	14-APR-2001
084	F-NS	Yes	Ibuprofen Osteo Bi-Flex Tums Menthol sore throat lozenges	Pulled muscle in back Left knee injury Heartburn Viral URI	200 mg 1-2 tabs 1 tab 1 lozenge	po po po po	6 times/day qd 4 times/month pm	17-MAR-2001 NOV-2000 1987 10-JUN-2001	03-APR-2001 ONGOING 12-APR-2001 13-JUN-2001

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-38
Concomitant Medications by Subject
(Page 11 of 17)

Subject Number	Subject Classification ^a	Any Medications Taken?	Drug	Indication	Dose	Route	Frequency	Start Date	Stop Date
085	F-NS	Yes	Ectrostep FE One A Day	Oral contraceptive	1 tab	po	qd	NOV-2000	ONGOING
				General health	1 tab	po	bid	APR-2001	ONGOING
086	F-NS	Yes	Advil Cold and Sinus Aytup Nitetime Orthotricyclen Tri-tab Thera-Flu Night Time	Cold symptoms	1 cap	po	bid	29-MAR-2001	30-MAR-2001
				Cold symptoms	2 tabs	po	qd	01-APR-2001	02-APR-2001
				Contraception	1 pill	po	qd	2000	ONGOING
				Rhinorrhea	1 packet	po	pm	08-MAY-2001	08-MAY-2001
087	F-NS	Yes	Multivitamin	Health supplement	1 tab	po	qd	2000	ONGOING
088	F-NS	Yes	Orthocyclen 28 day	Contraception	1 tab	po	qd	1996	ONGOING
089	F-NS	Yes	Tylenol	Root canal	650 mg	po	pm	21-MAY-2001	28-MAY-2001
			Ibuprofen	Root canal	400 mg	po	pm	28-MAY-2001	30-MAY-2001
			Lidocaine	Root canal	Unknown	sq	once	30-MAY-2001	30-MAY-2001
090	F-NS	Yes	Ecotrin	Prophylactic	81 mg	po	qd	MAR-2001	ONGOING
			Estriol	Menopause	2 mg	po	bid	12-MAR-2001	ONGOING
			Testosterone	Menopause	2 mg	po	bid	12-MAR-2001	11-JUN-2001
			Ibuprofen	Pain	200 mg	po	pm	1999	ONGOING
			Multi-vitamin	Supplement	1 tab	po	qd	2001	ONGOING
			Q-Carnitine Plus	Supplement	1 tab	po	qd	2000	ONGOING
			Bilberry herb	Supplement	1 tab	po	bid	2000	ONGOING
			Vitamin E	Supplement	400 iu	po	qd	1960	ONGOING
			Glucosamine Sulfate	Supplement	500 mg	po	pm	08-MAY-2001	ONGOING
			Chondroitine	Supplement	400 mg	po	pm	08-MAY-2001	ONGOING
091	F-NS	Yes	Vitamin E	General health	400 iu	po	qd	1990	ONGOING
			Vitamin C	General health	500 mg	po	qd	1990	ONGOING
			Multivitamin	General health	1 tab	po	qd	1990	ONGOING
			Vitamin B12	General health	50 mcg	po	qd	NOV-2000	ONGOING
			Calcium	General health	500 mg	po	qd	NOV-2000	ONGOING
092	F-NS	Yes	One daily vitamin	Health	1 tab	po	qd	01-APR-2001	ONGOING
			Ginseng Energy	Health	1 gel-tab	po	qd	01-APR-2001	ONGOING

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.3-38
Concomitant Medications by Subject
(Page 12 of 17)

Subject Number	Subject Classification ^a	Any Medications Taken?	Drug	Indication	Dose	Route	Frequency	Start Date	Stop Date
092	F-NS	Yes	Ibuprofen Ibuprofen	Tension Menstrual cramps	400 mg 200 mg	po po	q 10 days 3 times	1999 13-MAY-2001	ONGOING 14-MAY-2001
093	F-NS	Yes	Tylenol Acetaminophen Acetaminophen	Menstrual cramping Menstrual cramping Menstrual cramping	650 mg 1500 mg 1000 mg	po po po	once twice once	14-APR-2001 22-MAY-2001 21-MAY-2001	14-APR-2001 22-MAY-2001 21-MAY-2001
094	F-NS	No							
095	F-NS	Yes	Prempro Aspirin Hydrochloride Pseudoephedrine	Hormone replacement therapy Headache, aches Sinus congestion	1 tab 325 mg 30 mg	po po po	qd 1-2 per week 1-2 per week	DEC-1999 1998 1998	ONGOING ONGOING ONGOING
096	F-NS	Yes	Orthotricyclen Acetaminophen Ibuprofen Aspirin Diet fuel	Oral contraceptive General aches General aches Cold with aching To promote weight loss with exercise	1 tab 1000 mg 400 mg 650 mg 2 tabs	po po po po po	qd prn prn once 2-3 times/week	JAN-2001 1996 1996 26-MAR-2001 16-APR-2001	ONGOING ONGOING ONGOING 26-MAR-2001 ONGOING
097	F-NS	Yes	Demulen 1/35-28 Bufferin Vapor rub	Contraception Cold symptoms Cold symptoms	1 tab 2 tabs 1 app	po po top	qd bid qd	AUG-1998 15-APR-2001 16-APR-2001	ONGOING 18-APR-2001 17-APR-2001
098	F-NS	Yes	Motrin	Menstrual cramps	400 mg	po	prn	1998	ONGOING
099	F-NS	Yes	Loestrin Differin Metrocream Clindamycin	Contraception Acne Acne Acne	1 tab 1 app 1 app 1 app	po top top top	qd 2 times/week 2 times/week 2 times/week	1997 01-MAR-2001 01-MAR-2001 01-MAR-2001	ONGOING ONGOING ONGOING ONGOING
100	F-NS	No							
101	F-NS	Yes	Multivitamin	Supplement	1 tab	po	qd	1978	ONGOING
102	F-NS	Yes	Tylenol (simply sleep)	Sleep aid	50 mg	po	once	22-APR 2001	22-APR 2001

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-38
Concomitant Medications by Subject
(Page 13 of 17)

Subject Number	Subject Classification ^a	Any Medications Taken?	Drug	Indication	Dose	Route	Frequency	Start Date	Stop Date
102	F-NS	Yes	Norinyl	Birth control	1 tab	po	qd	MAR-2001	ONGOING
103	F-NS	Yes	Loestrin	Contraceptive	1.5 mg	po	qd	2000	ONGOING
104	M-NS	Yes	Aspirina Novalgina	Headache, fever Headache, fever	500 mg 500 mg	po po	once once	08-JUN-2001 08-JUN-2001	08-JUN-2001 08-JUN-2001
105	M-NS	Yes	Ascorbic Acid	Health	500 mg	po	qd	APR-2000	ONGOING
106	M-NS	No							
107	M-NS	No							
108	M-NS	No							
109	M-NS	Yes	Betameth DIP C-triam cream 0.1 Aquaphor 1:1	Dry skin Dry skin Dry skin	0.05% Unknown Unknown	top top top	pm pm pm	NOV-2000 NOV-2000 NOV-2000	ONGOING ONGOING ONGOING
110	M-NS	Yes	Nature made essential	Health	1 tab	po	qd	2000	ONGOING
111	M-NS	Yes	Ibuprofen	Headache	400 mg	po	once	10-APR-2001	10-APR-2001
112	M-NS	Yes	Vitamin E Avelox Zestril	General health Cough Hypertension	400 iu 400 mg 5 mg	po po po	qd qd qd	1996 03-APR-2001 02-DEC-2000	ONGOING 12-APR-2001 ONGOING
113	M-NS	No							
114	M-NS	Yes	Multivitamin pack one a day	Health	7 tabs	po	pm	17-MAR-2001	ONGOING
115	M-NS	Yes	One source multivitamin Vitamin B1	Health Mosquito bites prophylaxis	1 tab 1 tab	po po	qwk qd	JAN-2001 01-MAY-2001	MAR-2001 ONGOING
116	M-NS	Yes	Multivitamin	Health	1 tab	po	qd	NOV-2000	ONGOING

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Listing 16.5-38
Concomitant Medications by Subject
(Page 14 of 17)

Subject Number	Subject Classification ^a	Any Medications Taken?	Drug	Indication	Dose	Route	Frequency	Start Date	Stop Date
116	M-NS	Yes	Yellow fever vaccine	Travel to Africa	Unknown	im	x1	30-APR-2001	30-APR-2001
			Typhoid vaccine	Travel	0.5 cc	im	x1	30-APR-2001	30-APR-2001
			Polio vaccine	Travel	0.5 cc	im	x1	30-APR-2001	30-APR-2001
			Hepatitis A vaccine	Travel	1.0 cc	im	x1	30-APR-2001	30-APR-2001
			Hepatitis B vaccine	Travel	1.0 cc	im	x1	30-APR-2001	30-APR-2001
			MMR vaccine	Travel	0.5 cc	im	x1	30-APR-2001	30-APR-2001
117	M-NS	Yes	Multivitamin	Health	1 tab	po	qd	1989	ONGOING
			Cimetidine	Acid reduction	200 mg	po	once	11-APR-2001	11-APR-2001
			Naproxen Sodium	Sore shoulder	440 mg	po	once	12-APR-2001	12-APR-2001
			Tolnaftate (cream)	Athletes foot	1 %	top	qd	20-MAR-2001	ONGOING
			Glucosamine chondroitin	Health	1.5 g	po	qd	APR-2000	ONGOING
			Acetaminophen	Shoulder pain	650 mg	po	once	22-MAR-2001	22-MAR-2001
118	M-NS	Yes	Aspirin	Headache	1000 mg	po	2x month	Unknown	15-FEB-2001
			Vitamin C	Health	500 mg	po	qd	NOV-2000	13-JAN-2001
119	M-NS	No							
120	M-NS	No							
121	M-NS	Yes	Imipramine	Sleep/anxiety	30 mg	po	qd	1999	ONGOING
			Allegra	Allergies	60 mg	po	bid	1998	ONGOING
			Daily multivitamin	General health	1 tab	po	qd	1991	ONGOING
			Aspirin	Headache	650 mg	po	prn	Unknown	Unknown
122	M-NS	Yes	Pseudoephedrine	Nasal congestion	30 mg	po	2x	08-MAY-2001	08-MAY-2001
			ASA	Muscle pain	325 mg	po	prn	Unknown	15-APR-2001
			Pepto Bismol	Stomach pain	1/2-1 tab	po	prn	Unknown	11-APR-2001
123	M-NS	Yes	B complex	General health	1 tab	po	qd	2000	ONGOING
			Antioxidant vitamin supplement	General health	1 soft gel	po	qd	1996	ONGOING
			Vitamin C	General health	500 mg	po	bid	1996	ONGOING
			Odorless garlic	General health	73.5 mg	po	qd	2000	ONGOING
			Cod liver oil	General health	1 soft gel	po	qd	2000	ONGOING

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Listing 16.5-38
Concomitant Medications by Subject
(Page 15 of 17)

Subject Number	Subject Classification ^a	Any Medications Taken?	Drug	Indication	Dose	Route	Frequency	Start Date	Stop Date
123	M-NS	Yes	Ultramax - 46	General health	1 tab	po	qd	2000	ONGOING
			Saw palmetto	General health	900 mg	po	bid	1999	ONGOING
			Antioxidant formula	General health	1 soft gel	po	qd	2000	ONGOING
124	M-NS	No							
125	M-NS	Yes	Aleve	Headache	1 tab	po	once	18-APR-2001	18-APR-2001
			Naproxen	Back pain	500 mg	po	prn	12-MAY-2001	12-MAY-2001
			Cyclobenzaprine	Back pain	10 mg	po	prn	01-MAY-2001	ONGOING
			Roxicet	Migrane	325 mg	po	qd	13-JUN-2001	13-JUN-2001
			Amerge	Migrane	2.5 mg	po	qd	14-JUN-2001	14-JUN-2001
126	M-NS	Yes	Aspirin	Prophylaxis	81 mg	po	qd	1990	ONGOING
			Multivitamin	Supplement	1 tab	po	qd	1990	ONGOING
127	M-NS	No							
128	M-NS	Yes	Ibuprofen	Headache	200 mg	po	once	08-MAY-2001	08-MAY-2001
129	M-NS	Yes	Aspirin	Sore back	650 mg	po	once	15-APR-2001	15-APR-2001
			Acetaminophen	Headache	650 mg	po	once	10-APR-2001	10-APR-2001
130	M-NS	No							
131	M-NS	Yes	Histenol forte	Nasal congestion	2 tabs	po	twice	09-MAY-2001	09-MAY-2001
132	M-NS	No							
133	M-NS	No							
134	M-NS	Yes	Vicodin	Broken finger	1 tab	po	prn	23-APR-2001	28-APR-2001
			Fentanyl	Broken finger	50 mcg	iv	x1	18-MAY-2001	18-MAY-2001
			Hydromorphone	Broken finger	1 mg	iv	x1	18-MAY-2001	18-MAY-2001
			Propofol	Broken finger	200 mg	iv	x1	18-MAY-2001	18-MAY-2001
			Lidocaine	Broken finger	40 mg	iv	x1	18-MAY-2001	18-MAY-2001

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Listing 16.5-38
Concomitant Medications by Subject
(Page 16 of 17)

Subject Number	Subject Classification ^a	Any Medications Taken?	Drug	Indication	Dose	Route	Frequency	Start Date	Stop Date
134	M-NS	Yes	Midazolam	Broken finger	2 mg	iv	x1	18-MAY-2001	18-MAY-2001
			Droperidol	Broken finger	0.625 mg	iv	x1	18-MAY-2001	18-MAY-2001
			Cleocin	Broken finger	900 mg	iv	x1	18-MAY-2001	18-MAY-2001
			Nitrous oxide	Broken finger	Unknown	inh	x1	18-MAY-2001	18-MAY-2001
			Seroflurane	Broken finger	Unknown	inh	x1	18-MAY-2001	18-MAY-2001
			Desflurane	Broken finger	Unknown	inh	x1	18-MAY-2001	18-MAY-2001
			Dilaudid	Broken finger	0.4 mg	iv	x1	18-MAY-2001	18-MAY-2001
			Vicodin	Broken finger	2 tabs	po	10x	18-MAY-2001	21-MAY-2001
			Vicodin	Broken finger	2 tabs	po	x1	25-MAY-2001	25-MAY-2001
			Ibuprofen	HA	400 mg	po	x1	27-MAY-2001	27-MAY-2001
			Vicodin	Broken finger	1 tab	po	x1	12-JUN-2001	12-JUN-2001
135	M-NS	No							
500	F-NS	Yes	Ibuprofen	Headache	400 mg	po	once	21-APR-2001	21-APR-2001
			NcCon	Contraception	1 tab	po	qd	SEP-2000	ONGOING
501	F-NS	Yes	Vitamin E	Supplement	200 iu	po	qd	1980	ONGOING
			Chromium picolinate	Supplement	200 mcg	po	qd	2001	ONGOING
			Mela-cal	Supplement	1 tab	po	qd	2001	ONGOING
			Multivitamin	Supplement	1 tab	po	qd	2001	ONGOING
			CoQ 10	Supplement	1 tab	po	qd	2001	ONGOING
			Primrose oil	Supplement	500 mg	po	qd	2001	ONGOING
			B-6 Vitamin	Supplement	100 mg	po	qd	2001	ONGOING
			Flax oil	Supplement	1 tab	po	qd	2001	ONGOING
502	F-S	Yes	OPC-3 nutritional supplement	Health	3-4 caps	po	qd	1999	ONGOING
			Antioxidants	Health	1 cap	po	qd	1999	ONGOING
			Thermochrome	Wt. loss	2-3 tabs	po	qd	JAN-2001	ONGOING
			Aloe vera juice	Health	1-2 oz	po	qd	1999	ONGOING
			Digestive enzymes	Health	4 caps	po	qd	JAN-2001	ONGOING
503	F-S	Yes	Tri-Phasil	Birth control	1 tab	po	qd	DEC-2000	ONGOING
504	F-S	Yes	Womens prime multi	Health	2 tabs	po	qd	JAN-2001	ONGOING

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.S-38
Concomitant Medications by Subject
(Page 17 of 17)

Subject Number	Subject Classification ^a	Any Medications Taken?	Drug	Indication	Dose	Route	Frequency	Start Date	Stop Date
504	F-S	Yes	Loprox	Toenail fungus	1 app	top	bid	APR-2001	ONGOING
			Aspirin	Headache	325 mg	po	once/month	1981	ONGOING
505	F-NS	Yes	Tums with calcium	Supplement	2 tabs	po	bid	SEP-2000	ONGOING
			Tylenol	Finger laceration	650 mg	po	once	26-APR-2001	26-APR-2001
506	F-S	Yes	Zycam	Fluid in ears	2 sprays	in	3x	02-APR-2001	04-APR-2001
			Ibuprofen	Headaches, toothache	400-600 mg	po	prn	1998	ONGOING
			Aspirin	Headaches, muscle aches	650 mg	po	prn	1981	ONGOING
			Kava-Kava tea	Health	1/2 cup	po	1x	21-APR-2001	21-APR-2001
			Zomeg	Headache	2.5 mg	po	prn	05-JUN-2001	05-JUN-2001
			Vitamin C drink	Health	1 drink	po	1x	21-APR-2001	21-APR-2001

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-39
Subject Dispositions
(Page 1 of 8)

Subject Number	Subject Classification ^a	Completed/Withdrawn	Date	Investigator Comments
001	F-S	Completed	11-JUN-2001	
002	F-S	Completed	11-JUN-2001	
003	F-S	Completed	14-JUN-2001	
004	F-S	Completed	11-JUN-2001	
005	F-S	Completed	08-JUN-2001	
006	F-S	Completed	12-JUN-2001	
007	F-S	Completed	11-JUN-2001	
008	F-S	Completed	15-JUN-2001	
009	F-S	Completed	11-JUN-2001	
010	F-S	Withdrawn	15-MAY-2001	Subject withdrew consent, subject withdrew after Week 2 did not show for Week 3 or 6
011	F-S	Completed	17-JUN-2001	
012	F-S	Completed	16-JUN-2001	
013	F-S	Completed	11-JUN-2001	
014	F-S	Completed	11-JUN-2001	
015	F-S	Completed	11-JUN-2001	
016	F-S	Completed	11-JUN-2001	
017	F-S	Completed	14-JUN-2001	
018	F-S	Completed	12-JUN-2001	

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-39
Subject Dispositions
(Page 2 of 8)

Subject Number	Subject Classification ^a	Completed/Withdrawn	Date	Investigator Comments
019	F-S	Completed	13-JUN-2001	
020	F-S	Completed	13-JUN-2001	
021	F-S	Completed	17-JUN-2001	
022	F-S	Completed	12-JUN-2001	
023	F-S	Completed	11-JUN-2001	
024	F-S	Completed	13-JUN-2001	
025	F-S	Completed	17-JUN-2001	
026	F-S	Completed	16-JUN-2001	
027	F-S	Completed	13-JUN-2001	
028	F-S	Completed	12-JUN-2001	
029	F-S	Completed	15-JUN-2001	
030	F-S	Completed	12-JUN-2001	
031	F-S	Completed	15-JUN-2001	
032	F-S	Completed	18-JUN-2001	
033	F-S	Completed	18-JUN-2001	
034	F-S	Completed	18-JUN-2001	
035	F-S	Completed	13-JUN-2001	
036	M-S	Completed	11-JUN-2001	

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-39
Subject Dispositions
(Page 3 of 8)

Subject Number	Subject Classification ^a	Completed/Withdrawn	Date	Investigator Comments
037	M-S	Completed	13-JUN-2001	
038	M-S	Completed	11-JUN-2001	
039	M-S	Completed	11-JUN-2001	
040	M-S	Completed	17-JUN-2001	
041	M-S	Completed	13-JUN-2001	
042	M-S	Completed	11-JUN-2001	
043	M-S	Completed	11-JUN-2001	
044	M-S	Completed	14-JUN-2001	
045	M-S	Completed	11-JUN-2001	
046	M-S	Completed	12-JUN-2001	
047	M-S	Completed	13-JUN-2001	
048	M-S	Completed	12-JUN-2001	
049	M-S	Completed	11-JUN-2001	
050	M-S	Completed	18-JUN-2001	
051	M-S	Withdrawn	03 MAY 2001	Positive drug screen on enrollment
052	M-S	Completed	12-JUN-2001	
053	M-S	Withdrawn	03-MAY-2001	Positive drug screen at enrollment
054	M-S	Completed	13-JUN-2001	

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630437

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-39
Subject Dispositions
(Page 4 of 8)

Subject Number	Subject Classification ^a	Completed/Withdrawn	Date	Investigator Comments
055	M-S	Completed	13-JUN-2001	
056	M-S	Completed	16-JUN-2001	
057	M-S	Completed	17-JUN-2001	
058	M-S	Completed	18-JUN-2001	
059	M-S	Completed	16-JUN-2001	
060	M-S	Completed	14-JUN-2001	
061	M-S	Completed	14-JUN-2001	
062	M-S	Completed	14-JUN-2001	
063	M-S	Completed	15-JUN-2001	
065	M-S	Completed	16-JUN-2001	
066	M-S	Withdrawn	03-MAY-2001	Positive drug screen at enrollment 05/03/01
067	M-S	Completed	15-JUN-2001	
068	M-S	Completed	17-JUN-2001	
069	M-S	Completed	13-JUN-2001	
071	F-NS	Completed	12-JUN-2001	
072	F-NS	Completed	12-JUN-2001	
073	F-NS	Completed	13-JUN-2001	
074	F-NS	Completed	11-JUN-2001	

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630438

Draft 1: 24 July 2002

Page 15091 of 15132

Listing 16.5-39
Subject Dispositions
(Page 5 of 8)

Subject Number	Subject Classification ^a	Completed/Withdrawn	Date	Investigator Comments
075	F-NS	Completed	14-JUN-2001	
076	F-NS	Completed	11-JUN-2001	
077	F-NS	Completed	11-JUN-2001	
078	F-NS	Completed	13-JUN-2001	
079	F-NS	Completed	11-JUN-2001	
080	F-NS	Completed	11-JUN-2001	
081	F-NS	Completed	11-JUN-2001	
082	F-NS	Completed	18-JUN-2001	
083	F-NS	Completed	12-JUN-2001	
084	F-NS	Completed	13-JUN-2001	
085	F-NS	Completed	11-JUN-2001	
086	F-NS	Completed	12-JUN-2001	
087	F-NS	Completed	11-JUN-2001	
088	F-NS	Completed	11-JUN-2001	
089	F-NS	Completed	11-JUN-2001	
090	F-NS	Completed	12-JUN-2001	
091	F-NS	Completed	12-JUN-2001	
092	F-NS	Completed	14-JUN-2001	

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

Listing 16.5-39
Subject Dispositions
(Page 6 of 8)

Subject Number	Subject Classification ^a	Completed/Withdrawn	Date	Investigator Comments
093	F-NS	Completed	13-JUN-2001	
094	F-NS	Completed	13-JUN-2001	
095	F-NS	Completed	12-JUN-2001	
096	F-NS	Completed	17-JUN-2001	
097	F-NS	Completed	16-JUN-2001	
098	F-NS	Completed	11-JUN-2001	
099	F-NS	Completed	11-JUN-2001	
100	F-NS	Completed	14-JUN-2001	
101	F-NS	Completed	17-JUN-2001	
102	F-NS	Completed	12-JUN-2001	
103	F-NS	Completed	18-JUN-2001	
104	M-NS	Completed	11-JUN-2001	
105	M-NS	Completed	14-JUN-2001	
106	M-NS	Completed	11-JUN-2001	
107	M-NS	Completed	16-JUN-2001	
108	M-NS	Completed	13-JUN-2001	
109	M-NS	Completed	11-JUN-2001	
110	M-NS	Completed	12-JUN-2001	

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

Listing 16.5-39
Subject Dispositions
(Page 7 of 8)

Subject Number	Subject Classification ^a	Completed/Withdrawn	Date	Investigator Comments
111	M-NS	Completed	11-JUN-2001	
112	M-NS	Completed	11-JUN-2001	
113	M-NS	Withdrawn	15-MAY-2001	Subject dropped out of study before completing Week 3 due to family emergency
114	M-NS	Completed	14-JUN-2001	
115	M-NS	Completed	15-JUN-2001	
116	M-NS	Completed	08-JUN-2001	
117	M-NS	Completed	13-JUN-2001	
118	M-NS	Completed	12-JUN-2001	
119	M-NS	Completed	12-JUN-2001	
120	M-NS	Completed	11-JUN-2001	
121	M-NS	Completed	11-JUN-2001	
122	M-NS	Completed	13-JUN-2001	
123	M-NS	Completed	12-JUN-2001	
124	M-NS	Completed	13-JUN-2001	
125	M-NS	Completed	18-JUN-2001	
126	M-NS	Completed	12-JUN-2001	
127	M-NS	Completed	11-JUN-2001	
128	M-NS	Completed	13-JUN-2001	

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

PM3006630441

Listing 16.5-39
Subject Dispositions
(Page 8 of 8)

Subject Number	Subject Classification ^a	Completed/Withdrawn	Date	Investigator Comments
129	M-NS	Completed	11-JUN-2001	
130	M-NS	Completed	13-JUN-2001	
131	M-NS	Completed	12-JUN-2001	
132	M-NS	Completed	15-JUN-2001	
133	M-NS	Completed	14-JUN-2001	
134	M-NS	Completed	18-JUN-2001	
135	M-NS	Completed	12-JUN-2001	Subject randomized to incorrect group should be non-smoker group, Subject #064 will become #135
500	F-NS	Completed	11-JUN-2001	
501	F-NS	Completed	14-JUN-2001	
502	F-S	Completed	14-JUN-2001	
503	F-S	Completed	11-JUN-2001	
504	F-S	Completed	12-JUN-2001	
505	F-NS	Completed	12-JUN-2001	
506	F-S	Completed	11-JUN-2001	

^a Subject Classification: M-NS—Male, Non-Smoker; M-S—Male, Smoker; F-NS—Female, Non-Smoker; F-S—Female, Smoker.

RSR

Protocol No. PM-8450

Covance CRU Study No. 12226-8450

16.6 Individual Subject Data Listings (Smoker Pertinent Data)

Listing 16.6-1
Duration of Smoking for Smokers by Subject
(Page 1 of 5)

Subject Number	Subject Classification ^a	Approximate Duration ^b (years)
001	F-S	13
002	F-S	19
003	F-S	No Response
004	F-S	15
005	F-S	4
006	F-S	30
007	F-S	23
008	F-S	20
009	F-S	37
010	F-S	9
011	F-S	38
012	F-S	20
013	F-S	17
014	F-S	13
015	F-S	2
016	F-S	27
017	F-S	7

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b Approximate Duration is as reported or as calculated from the difference between Screening and the reported start date to the nearest number of years. Where there is only a year reported, January 1st was used for the calculation. Where there is a month and year reported, the first of the reported month was used for the calculation.

PM3006630444

Listing 16.6-1
Duration of Smoking for Smokers by Subject
(Page 2 of 5)

Subject Number	Subject Classification ^a	Approximate Duration ^b (years)
018	F-S	10
019	F-S	7
020	F-S	23
021	F-S	8
022	F-S	14
023	F-S	28
024	F-S	27
025	F-S	20
026	F-S	38
027	F-S	26
028	F-S	6
029	F-S	5
030	F-S	26
031	F-S	5
032	F-S	9
033	F-S	5
034	F-S	22

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b Approximate Duration is as reported or as calculated from the difference between Screening and the reported start date to the nearest number of years. Where there is only a year reported, January 1st was used for the calculation. Where there is a month and year reported, the first of the reported month was used for the calculation.

Listing 16.6-1
 Duration of Smoking for Smokers by Subject
 (Page 3 of 5)

Subject Number	Subject Classification ^a	Approximate Duration ^b (years)
035	F-S	23
036	M-S	24
037	M-S	2
038	M-S	15
039	M-S	41
040	M-S	6
041	M-S	23
042	M-S	5
043	M-S	13
044	M-S	17
045	M-S	11
046	M-S	9
047	M-S	12
048	M-S	8
049	M-S	52
050	M-S	18
051	M-S	2

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b Approximate Duration is as reported or as calculated from the difference between Screening and the reported start date to the nearest number of years. Where there is only a year reported, January 1st was used for the calculation. Where there is a month and year reported, the first of the reported month was used for the calculation.

PM3006630446

Listing 16.6-1
Duration of Smoking for Smokers by Subject
(Page 4 of 5)

Subject Number	Subject Classification ^a	Approximate Duration ^b (years)
052	M-S	9
053	M-S	26
054	M-S	6
055	M-S	28
056	M-S	30
057	M-S	7
058	M-S	8
059	M-S	26
060	M-S	5
061	M-S	4
062	M-S	28
063	M-S	10
065	M-S	5
066	M-S	3
067	M-S	10
068	M-S	15
069	M-S	6

^a Subject Classification: M-NS=Male, Non-Smoker; M-S=Male, Smoker; F-NS=Female, Non-Smoker; F-S=Female, Smoker.

^b Approximate Duration is as reported or as calculated from the difference between Screening and the reported start date to the nearest number of years. Where there is only a year reported, January 1st was used for the calculation. Where there is a month and year reported, the first of the reported month was used for the calculation.

PM3006630447

Listing 16.6-1
Duration of Smoking for Smokers by Subject
(Page 5 of 5)

Subject Number	Subject Classification ^a	Approximate Duration ^b (years)
502	F-S	24
503	F-S	9
504	F-S	40
506	F-S	3

^a Subject Classification: M-NS: Male, Non-Smoker; M-S: Male, Smoker; F-NS: Female, Non-Smoker; F-S: Female, Smoker.

^b Approximate Duration is as reported or as calculated from the difference between Screening and the reported start date to the nearest number of years. Where there is only a year reported, January 1st was used for the calculation. Where there is a month and year reported, the first of the reported month was used for the calculation.

Listing 16.6-2
Cigarette Collection by Subject
(Page 1 of 10)

Subject Number	Subject Classification ^a	Timepoint	Start Date	Stop Date	Time of Last Cigarette Prior to Visit	Number Smoked Per Diary	Number Butts/Filters Collected
001	F-S	Week 1	06-MAY-2001	09-MAY-2001	07:02	57	57
		Week 2	11-MAY-2001	14-MAY-2001	06:57	49	47
		Week 3	19-MAY-2001	22-MAY-2001	06:55	53	53
		Week 6	08-JUN-2001	11-JUN-2001	06:55	56	54
002	F-S	Week 1	06-MAY-2001	09-MAY-2001	05:45	68	68
		Week 2	11-MAY-2001	14-MAY-2001	06:55	65	62
		Week 3	21-MAY-2001	24-MAY-2001	06:10	47	47
		Week 6	08-JUN-2001	11-JUN-2001	05:43	57	57
003	F-S	Week 1	08-MAY-2001	11-MAY-2001	13:45	14	18
		Week 2	15-MAY-2001	18-MAY-2001	11:09	21	21
		Week 3	21-MAY-2001	24-MAY-2001	11:50	15	14
		Week 6	11-JUN-2001	14-JUN-2001	Unknown	15	16
004	F-S	Week 1	06-MAY-2001	09-MAY-2001	12:45	30	31
		Week 2	11-MAY-2001	14-MAY-2001	08:32	35	35
		Week 3	19-MAY-2001	22-MAY-2001	11:10	36	36
		Week 6	08-JUN-2001	11-JUN-2001	11:20	38	38
005	F-S	Week 1	06-MAY-2001	09-MAY-2001	07:20	13	13
		Week 2	11-MAY-2001	14-MAY-2001	Unknown	18	17
		Week 3	20-MAY-2001	23-MAY-2001	Unknown	12	12
		Week 6	05-JUN-2001	08-JUN-2001	06:15	12	13
006	F-S	Week 1	06-MAY-2001	09-MAY-2001	07:06	60	60
		Week 2	12-MAY-2001	15-MAY-2001	12:33	59	60
		Week 3	19-MAY-2001	22-MAY-2001	10:30	69	68
		Week 6	09-JUN-2001	12-JUN-2001	12:50	62	61
007	F-S	Week 1	06-MAY-2001	09-MAY-2001	14:00	51	46
		Week 2	14-MAY-2001	17-MAY-2001	13:27	70	51
		Week 3	22-MAY-2001	25-MAY-2001	08:00	65	60
		Week 6	08-JUN-2001	11-JUN-2001	08:00	69	60

^a Subject Classification: M-S=Male, Smoker; F-S=Female, Smoker.

Listing 16.6-2
Cigarette Collection by Subject
(Page 2 of 10)

Subject Number	Subject Classification ^a	Timepoint	Start Date	Stop Date	Time of Last Cigarette Prior to Visit	Number Smoked Per Diary	Number Butts/Filters Collected
008	F-S	Week 1	11-MAY-2001	14-MAY-2001	09:45	77	77
		Week 2	15-MAY-2001	18-MAY-2001	09:20	63	64
		Week 3	21-MAY-2001	24-MAY-2001	08:10	64	63
		Week 6	12-JUN-2001	15-JUN-2001	09:40	73	72
009	F-S	Week 1	06-MAY-2001	09-MAY-2001	08:10	38	40
		Week 2	11-MAY-2001	14-MAY-2001	12:21	45	46
		Week 3	18-MAY-2001	21-MAY-2001	12:15	46	52
		Week 6	08-JUN-2001	11-JUN-2001	12:10	38	46
010	F-S	Week 1	08-MAY-2001	11-MAY-2001	14:30	7	8
		Week 2	12-MAY-2001	15-MAY-2001	14:11	12	15
011	F-S	Week 1	06-MAY-2001	09-MAY-2001	05:30	91	92
		Week 2	17-MAY-2001	20-MAY-2001	12:00	84	84
		Week 3	22-MAY-2001	25-MAY-2001	09:00	67	67
		Week 6	14-JUN-2001	17-JUN-2001	11:05	76	76
012	F-S	Week 1	06-MAY-2001	09-MAY-2001	05:45	83	69
		Week 2	13-MAY-2001	16-MAY-2001	12:02	71	75
		Week 3	21-MAY-2001	24-MAY-2001	10:20	67	80
		Week 6	13-JUN-2001	16-JUN-2001	10:45	69	69
013	F-S	Week 1	06-MAY-2001	09-MAY-2001	08:10	66	66
		Week 2	11-MAY-2001	14-MAY-2001	08:31	72	72
		Week 3	20-MAY-2001	21-MAY-2001	08:40	69	70
		Week 6	08-JUN-2001	11-JUN-2001	08:20	73	73
014	F-S	Week 1	06-MAY-2001	09-MAY-2001	08:05	56	56
		Week 2	11-MAY-2001	14-MAY-2001	07:50	56	56
		Week 3	18-MAY-2001	21-MAY-2001	08:04	53	53
		Week 6	08-JUN-2001	11-JUN-2001	07:56	51	54
015	F-S	Week 1	07-MAY-2001	09-MAY-2001	09:00	9	9
		Week 2	11-MAY-2001	14-MAY-2001	07:21	13	5
		Week 3	18-MAY-2001	21-MAY-2001	09:00	14	14
		Week 6	08-JUN-2001	11-JUN-2001	08:00	10	10

^a Subject Classification: M-S=Male, Smoker; F-S=Female, Smoker.

Listing 16.6-2
Cigarette Collection by Subject
(Page 3 of 10)

Subject Number	Subject Classification ^a	Timepoint	Start Date	Stop Date	Time of Last Cigarette Prior to Visit	Number Smoked Per Diary	Number Butts/Filters Collected
016	F-S	Week 1	06-MAY-2001	09-MAY-2001	06:45	31	33
		Week 2	12-MAY-2001	15-MAY-2001	11:40	34	34
		Week 3	19-MAY-2001	22-MAY-2001	11:45	34	34
		Week 6	08-JUN-2001	11-JUN-2001	11:35	46	46
017	F-S	Week 1	06-MAY-2001	09-MAY-2001	08:45	74	76
		Week 2	22-MAY-2001	25-MAY-2001	08:16	72	71
		Week 3	27-MAY-2001	30-MAY-2001	07:45	71	72
		Week 6	11-JUN-2001	14-JUN-2001	08:40	79	74
018	F-S	Week 1	06-MAY-2001	09-MAY-2001	06:40	23	23
		Week 2	12-MAY-2001	15-MAY-2001	06:42	27	27
		Week 3	19-MAY-2001	22-MAY-2001	06:45	29	29
		Week 6	09-JUN-2001	12-JUN-2001	11:35	22	21
019	F-S	Week 1	08-MAY-2001	11-MAY-2001	11:45	15	15
		Week 2	14-MAY-2001	17-MAY-2001	06:40	14	14
		Week 3	19-MAY-2001	22-MAY-2001	06:55	15	15
		Week 6	10-JUN-2001	13-JUN-2001	09:00	17	17
020	F-S	Week 1	06-MAY-2001	09-MAY-2001	10:35	101	102
		Week 2	13-MAY-2001	16-MAY-2001	10:25	96	96
		Week 3	20-MAY-2001	23-MAY-2001	10:30	98	98
		Week 6	10-JUN-2001	13-JUN-2001	10:19	73	97
021	F-S	Week 1	07-MAY-2001	10-MAY-2001	14:00	34	33
		Week 2	11-MAY-2001	14-MAY-2001	14:26	19	22
		Week 3	21-MAY-2001	24-MAY-2001	14:00	29	27
		Week 6	14-JUN-2001	17-JUN-2001	11:00	16	14
022	F-S	Week 1	08-MAY-2001	10-MAY-2001	06:10	48	44
		Week 2	14-MAY-2001	17-MAY-2001	06:00	63	64
		Week 3	21-MAY-2001	24-MAY-2001	05:40	42	42
		Week 6	09-JUN-2001	12-JUN-2001	05:50	66	65

^a Subject Classification: M-S=Male, Smoker; F-S=Female, Smoker.

Listing 16.6-2
Cigarette Collection by Subject
(Page 4 of 10)

Subject Number	Subject Classification ^a	Timepoint	Start Date	Stop Date	Time of Last Cigarette Prior to Visit	Number Smoked Per Diary	Number Butts/Filters Collected
023	F-S	Week 1	07-MAY-2001	09-MAY-2001	06:20	45	44
		Week 2	14-MAY-2001	17-MAY-2001	06:34	30	30
		Week 3	21-MAY-2001	24-MAY-2001	05:45	25	25
		Week 6	08-JUN-2001	11-JUN-2001	15:30	25	16
024	F-S	Week 1	08-MAY-2001	11-MAY-2001	06:50	49	54
		Week 2	15-MAY-2001	18-MAY-2001	06:35	44	45
		Week 3	22-MAY-2001	25-MAY-2001	08:13	49	49
		Week 6	10-JUN-2001	13-JUN-2001	06:50	39	39
025	F-S	Week 1	07-MAY-2001	10-MAY-2001	10:30	33	35
		Week 2	17-MAY-2001	20-MAY-2001	08:30	20	26
		Week 3	22-MAY-2001	25-MAY-2001	11:00	36	36
		Week 6	14-JUN-2001	17-JUN-2001	11:20	46	46
026	F-S	Week 1	08-MAY-2001	11-MAY-2001	10:30	83	88
		Week 2	11-MAY-2001	14-MAY-2001	09:58	84	82
		Week 3	21-MAY-2001	24-MAY-2001	10:55	91	92
		Week 6	13-JUN-2001	16-JUN-2001	10:55	83	82
027	F-S	Week 1	08-MAY-2001	11-MAY-2001	08:20	49	47
		Week 2	13-MAY-2001	16-MAY-2001	10:17	49	48
		Week 3	18-MAY-2001	21-MAY-2001	08:50	45	45
		Week 6	10-JUN-2001	13-JUN-2001	10:03	40	41
028	F-S	Week 1	08-MAY-2001	11-MAY-2001	08:40	67	67
		Week 2	14-MAY-2001	17-MAY-2001	08:41	68	73
		Week 3	21-MAY-2001	24-MAY-2001	08:45	72	72
		Week 6	09-JUN-2001	12-JUN-2001	09:00	68	68
029	F-S	Week 1	08-MAY-2001	11-MAY-2001	07:00	50	72
		Week 2	13-MAY-2001	16-MAY-2001	08:48	56	55
		Week 3	18-MAY-2001	21-MAY-2001	09:45	50	50
		Week 6	12-JUN-2001	15-JUN-2001	09:45	50	49

^a Subject Classification: M-S=Male, Smoker; F-S=Female, Smoker.

Listing 16.6-2
Cigarette Collection by Subject
(Page 5 of 10)

Subject Number	Subject Classification ^a	Timepoint	Start Date	Stop Date	Time of Last Cigarette Prior to Visit	Number Smoked Per Diary	Number Butts/Filters Collected
030	F-S	Week 1	07-MAY-2001	10-MAY-2001	10:25	63	44
		Week 2	11-MAY-2001	14-MAY-2001	06:32	61	62
		Week 3	18-MAY-2001	21-MAY-2001	06:52	62	62
		Week 6	09-JUN-2001	12-JUN-2001	06:05	63	62
031	F-S	Week 1	07-MAY-2001	10-MAY-2001	10:15	17	17
		Week 2	12-MAY-2001	15-MAY-2001	NA	16	16
		Week 3	20-MAY-2001	23-MAY-2001	NA	5	5
		Week 6	12-JUN-2001	15-JUN-2001	09:00	2	2
032	F-S	Week 1	08-MAY-2001	11-MAY-2001	14:10	48	48
		Week 2	17-MAY-2001	20-MAY-2001	08:56	27	28
		Week 3	22-MAY-2001	25-MAY-2001	08:30	28	29
		Week 6	15-JUN-2001	18-JUN-2001	05:45	30	30
033	F-S	Week 1	08-MAY-2001	11-MAY-2001	10:00	48	48
		Week 2	12-MAY-2001	15-MAY-2001	22:46	32	32
		Week 3	19-MAY-2001	22-MAY-2001	00:00	62	63
		Week 6	15-JUN-2001	18-JUN-2001	NA	0	0
034	F-S	Week 1	08-MAY-2001	11-MAY-2001	14:40	46	47
		Week 2	17-MAY-2001	20-MAY-2001	08:47	68	71
		Week 3	27-MAY-2001	30-MAY-2001	08:10	47	45
		Week 6	15-JUN-2001	18-JUN-2001	11:56	37	38
035	F-S	Week 1	07-MAY-2001	10-MAY-2001	04:30	52	51
		Week 2	13-MAY-2001	16-MAY-2001	05:11	39	41
		Week 3	19-MAY-2001	22-MAY-2001	05:45	53	55
		Week 6	10-JUN-2001	13-JUN-2001	05:15	65	68
036	M-S	Week 1	06-MAY-2001	09-MAY-2001	06:30	51	51
		Week 2	12-MAY-2001	15-MAY-2001	07:02	28	28
		Week 3	19-MAY-2001	22-MAY-2001	06:10	44	43
		Week 6	08-JUN-2001	11-JUN-2001	06:30	56	56

^a Subject Classification: M-S=Male, Smoker; F-S=Female, Smoker.

Listing 16.6-2
Cigarette Collection by Subject
(Page 6 of 10)

Subject Number	Subject Classification ^a	Timepoint	Start Date	Stop Date	Time of Last Cigarette Prior to Visit	Number Smoked Per Diary	Number Butts/Filters Collected
037	M-S	Week 1	07-MAY-2001	10-MAY-2001	09:30	38	41
		Week 2	13-MAY-2001	16-MAY-2001	06:02	45	45
		Week 3	19-MAY-2001	22-MAY-2001	03:30	42	32
		Week 6	10-JUN-2001	13-JUN-2001	11:00	39	49
038	M-S	Week 1	06-MAY-2001	09-MAY-2001	08:35	55	53
		Week 2	11-MAY-2001	14-MAY-2001	08:15	35	35
		Week 3	18-MAY-2001	21-MAY-2001	08:45	73	73
		Week 6	08-JUN-2001	11-JUN-2001	08:30	15	15
039	M-S	Week 1	06-MAY-2001	09-MAY-2001	06:10	105	102
		Week 2	11-MAY-2001	14-MAY-2001	06:00	113	108
		Week 3	18-MAY-2001	21-MAY-2001	06:15	121	121
		Week 6	08-JUN-2001	11-JUN-2001	06:05	101	101
040	M-S	Week 1	13-MAY-2001	16-MAY-2001	09:15	28	29
		Week 2	17-MAY-2001	20-MAY-2001	07:59	18	18
		Week 3	21-MAY-2001	24-MAY-2001	12:40	18	18
		Week 6	14-JUN-2001	17-JUN-2001	23:00	17	17
041	M-S	Week 1	08-MAY-2001	11-MAY-2001	12:30	39	44
		Week 2	11-MAY-2001	14-MAY-2001	09:14	27	27
		Week 3	18-MAY-2001	21-MAY-2001	13:30	34	38
		Week 6	10-JUN-2001	13-JUN-2001	08:50	38	37
042	M-S	Week 1	07-MAY-2001	10-MAY-2001	11:25	24	25
		Week 2	11-MAY-2001	14-MAY-2001	12:51	44	44
		Week 3	21-MAY-2001	24-MAY-2001	11:30	41	41
		Week 6	08-JUN-2001	11-JUN-2001	11:36	60	60
043	M-S	Week 1	06-MAY-2001	09-MAY-2001	09:20	75	75
		Week 2	11-MAY-2001	14-MAY-2001	09:38	75	75
		Week 3	20-MAY-2001	23-MAY-2001	09:10	55	58
		Week 6	08-JUN-2001	11-JUN-2001	09:10	66	80

^a Subject Classification: M-S=Male, Smoker; F-S=Female, Smoker.

Listing 16.6-2
Cigarette Collection by Subject
(Page 7 of 10)

Subject Number	Subject Classification ^a	Timepoint	Start Date	Stop Date	Time of Last Cigarette Prior to Visit	Number Smoked Per Diary	Number Butts/Filters Collected
044	M-S	Week 1	06-MAY-2001	09-MAY-2001	11:45	35	32
		Week 2	14-MAY-2001	17-MAY-2001	11:53	33	32
		Week 3	20-MAY-2001	23-MAY-2001	11:45	30	30
		Week 6	11-JUN-2001	14-JUN-2001	12:00	30	30
045	M-S	Week 1	07-MAY-2001	10-MAY-2001	14:30	47	47
		Week 2	14-MAY-2001	17-MAY-2001	12:10	29	29
		Week 3	21-MAY-2001	24-MAY-2001	12:20	27	25
		Week 6	08-JUN-2001	11-JUN-2001	14:40	20	20
046	M-S	Week 1	08-MAY-2001	11-MAY-2001	09:05	60	62
		Week 2	11-MAY-2001	14-MAY-2001	08:27	55	57
		Week 3	18-MAY-2001	21-MAY-2001	08:10	57	58
		Week 6	09-JUN-2001	12-JUN-2001	08:55	56	57
047	M-S	Week 1	07-MAY-2001	10-MAY-2001	13:45	25	25
		Week 2	13-MAY-2001	16-MAY-2001	09:47	22	22
		Week 3	20-MAY-2001	23-MAY-2001	09:45	26	26
		Week 6	10-JUN-2001	13-JUN-2001	09:49	27	27
048	M-S	Week 1	07-MAY-2001	10-MAY-2001	08:30	40	40
		Week 2	12-MAY-2001	15-MAY-2001	23:12	36	47
		Week 3	18-MAY-2001	21-MAY-2001	08:00	30	41
		Week 6	09-JUN-2001	12-JUN-2001	01:00	38	38
049	M-S	Week 1	08-MAY-2001	11-MAY-2001	05:45	61	59
		Week 2	12-MAY-2001	15-MAY-2001	07:33	62	64
		Week 3	20-MAY-2001	23-MAY-2001	08:05	69	72
		Week 6	08-JUN-2001	11-JUN-2001	08:30	45	43
050	M-S	Week 1	08-MAY-2001	11-MAY-2001	07:00	10	10
		Week 2	11-MAY-2001	14-MAY-2001	06:19	9	9
		Week 3	20-MAY-2001	23-MAY-2001	06:30	10	10
		Week 6	15-JUN-2001	18-JUN-2001	06:39	9	11

^a Subject Classification: M-S=Male, Smoker; F-S=Female, Smoker.

Listing 16.6-2
Cigarette Collection by Subject
(Page 8 of 10)

Subject Number	Subject Classification ^a	Timepoint	Start Date	Stop Date	Time of Last Cigarette Prior to Visit	Number Smoked Per Diary	Number Butts/Filters Collected
052	M-S	Week 1	08-MAY-2001	11-MAY-2001	01:00	42	42
		Week 2	15-MAY-2001	18-MAY-2001	09:40	44	46
		Week 3	21-MAY-2001	24-MAY-2001	08:00	40	41
		Week 6	09-JUN-2001	12-JUN-2001	11:45	40	40
054	M-S	Week 1	07-MAY-2001	10-MAY-2001	10:00	67	67
		Week 2	13-MAY-2001	16-MAY-2001	05:25	61	60
		Week 3	20-MAY-2001	23-MAY-2001	11:00	42	43
		Week 6	10-JUN-2001	13-JUN-2001	11:20	59	56
055	M-S	Week 1	07-MAY-2001	10-MAY-2001	08:55	69	68
		Week 2	12-MAY-2001	15-MAY-2001	06:48	61	59
		Week 3	20-MAY-2001	23-MAY-2001	06:30	60	60
		Week 6	10-JUN-2001	13-JUN-2001	06:40	55	55
056	M-S	Week 1	08-MAY-2001	11-MAY-2001	10:20	25	25
		Week 2	17-MAY-2001	20-MAY-2001	06:05	34	34
		Week 3	22-MAY-2001	25-MAY-2001	06:00	37	40
		Week 6	13-JUN-2001	16-JUN-2001	07:45	25	25
057	M-S	Week 1	07-MAY-2001	10-MAY-2001	07:30	62	62
		Week 2	12-MAY-2001	15-MAY-2001	13:26	51	44
		Week 3	18-MAY-2001	21-MAY-2001	13:30	44	45
		Week 6	14-JUN-2001	17-JUN-2001	11:45	52	51
058	M-S	Week 1	08-MAY-2001	11-MAY-2001	09:00	29	32
		Week 2	17-MAY-2001	20-MAY-2001	11:22	40	47
		Week 3	22-MAY-2001	25-MAY-2001	08:00	21	20
		Week 6	15-JUN-2001	18-JUN-2001	08:50	29	29
059	M-S	Week 1	07-MAY-2001	10-MAY-2001	12:20	67	67
		Week 2	13-MAY-2001	16-MAY-2001	06:47	78	77
		Week 3	19-MAY-2001	22-MAY-2001	08:05	56	56
		Week 6	13-JUN-2001	16-JUN-2001	08:15	75	80

^a Subject Classification: M-S=Male, Smoker; F-S=Female, Smoker.

Listing 16.6-2
Cigarette Collection by Subject
(Page 9 of 10)

Subject Number	Subject Classification ^a	Timepoint	Start Date	Stop Date	Time of Last Cigarette Prior to Visit	Number Smoked Per Diary	Number Butts/Filters Collected
060	M-S	Week 1	08-MAY-2001	11-MAY-2001	11:55	47	52
		Week 2	15-MAY-2001	18-MAY-2001	10:11	50	52
		Week 3	22-MAY-2001	25-MAY-2001	11:35	55	53
		Week 6	11-JUN-2001	14-JUN-2001	08:20	42	38
061	M-S	Week 1	08-MAY-2001	11-MAY-2001	14:30	56	57
		Week 2	14-MAY-2001	17-MAY-2001	07:46	42	42
		Week 3	20-MAY-2001	23-MAY-2001	09:30	25	26
		Week 6	11-JUN-2001	14-JUN-2001	10:00	50	50
062	M-S	Week 1	08-MAY-2001	11-MAY-2001	11:20	85	87
		Week 2	13-MAY-2001	16-MAY-2001	11:48	84	85
		Week 3	21-MAY-2001	24-MAY-2001	11:20	85	84
		Week 6	11-JUN-2001	14-JUN-2001	12:10	81	85
063	M-S	Week 1	07-MAY-2001	10-MAY-2001	07:30	16	21
		Week 2	14-MAY-2001	20-MAY-2001	10:06	48	49
		Week 3	22-MAY-2001	25-MAY-2001	06:40	26	26
		Week 6	12-JUN-2001	15-JUN-2001	06:45	38	44
065	M-S	Week 1	07-MAY-2001	10-MAY-2001	03:30	33	32
		Week 2	14-MAY-2001	17-MAY-2001	00:39	32	30
		Week 3	19-MAY-2001	22-MAY-2001	11:20	28	25
		Week 6	13-JUN-2001	16-JUN-2001	NA	0	0
067	M-S	Week 1	08-MAY-2001	11-MAY-2001	01:00	16	13
		Week 2	14-MAY-2001	17-MAY-2001	21:35	9	8
		Week 3	21-MAY-2001	24-MAY-2001	00:30	9	10
		Week 6	12-JUN-2001	15-JUN-2001	10:15	15	15
068	M-S	Week 1	08-MAY-2001	11-MAY-2001	11:10	88	86
		Week 2	17-MAY-2001	20-MAY-2001	09:00	74	82
		Week 3	22-MAY-2001	25-MAY-2001	09:00	86	93
		Week 6	14-JUN-2001	17-JUN-2001	08:30	91	92

^a Subject Classification: M-S=Male, Smoker; F-S=Female, Smoker.

Listing 16.6-2
Cigarette Collection by Subject
(Page 10 of 10)

Subject Number	Subject Classification ^a	Timepoint	Start Date	Stop Date	Time of Last Cigarette Prior to Visit	Number Smoked Per Diary	Number Butts/Filters Collected
069	M-S	Week 1	12-MAY-2001	15-MAY-2001	10:00	77	65
		Week 2	19-MAY-2001	22-MAY-2001	13:00	45	53
		Week 3	01-JUN-2001	04-JUN-2001	11:00	37	37
		Week 6	09-JUN-2001	12-JUN-2001	05:30	39	54
502	F-S	Week 1	11-MAY-2001	14-MAY-2001	07:14	36	39
		Week 2	17-MAY-2001	20-MAY-2001	09:43	37	36
		Week 3	24-MAY-2001	24-MAY-2001	08:00	43	44
		Week 6	11-JUN-2001	14-JUN-2001	08:15	33	37
503	F-S	Week 1	07-MAY-2001	10-MAY-2001	09:30	77	77
		Week 2	13-MAY-2001	16-MAY-2001	11:00	66	66
		Week 3	18-MAY-2001	21-MAY-2001	10:30	54	54
		Week 6	08-JUN-2001	11-JUN-2001	09:45	50	52
504	F-S	Week 1	08-MAY-2001	11-MAY-2001	12:25	81	82
		Week 2	12-MAY-2001	15-MAY-2001	Unknown	91	91
		Week 3	21-MAY-2001	24-MAY-2001	11:45	97	98
		Week 6	09-JUN-2001	12-JUN-2001	11:50	83	84
506	F-S	Week 1	08-MAY-2001	11-MAY-2001	12:30	4	8
		Week 2	14-MAY-2001	17-MAY-2001	Unknown	3	3
		Week 3	21-MAY-2001	24-MAY-2001	12:40	15	15
		Week 6	08-JUN-2001	11-JUN-2001	22:00	8	11

^a Subject Classification: M-S=Male, Smoker; F-S=Female, Smoker.

Listing 16.6-3
Self-Exposed FTC Values for Smokers by Subject
(Page 1 of 9)

Subject Number	Gender	Timepoint	Cigarettes per Day	Percentage of Use	Preferred Brand			Percentage of Use	Alternate Brand(s)			Totals ^a		
					TAR (mg/cig)	NICOTINE (mg/cig)	CO (mg/cig)		TAR (mg/cig)	NICOTINE (mg/cig)	CO (mg/cig)	TAR (mg)	NICOTINE (mg)	CO (mg)
001	Female	Enrollment	20	100.0	5	0.5	7	0.0	0	0.0	0	100	10.0	140
		Week 1	17	100.0	5	0.5	7	0.0	0	0.0	0	85	8.5	119
		Week 2	17	100.0	5	0.5	7	0.0	0	0.0	0	85	8.5	119
		Week 3	17	100.0	5	0.5	7	0.0	0	0.0	0	85	8.5	119
		Week 6	17	100.0	5	0.5	7	0.0	0	0.0	0	85	8.5	119
002	Female	Enrollment	20	95.0	6	0.5	8	5.0	5	0.5	6	119	10.0	158
		Week 1	22	100.0	6	0.5	8	0.0	0	0.0	0	132	11.0	176
		Week 2	20	100.0	6	0.5	8	0.0	0	0.0	0	120	10.0	160
		Week 3	15	100.0	6	0.5	8	0.0	0	0.0	0	90	7.5	120
		Week 6	20	100.0	6	0.5	8	0.0	0	0.0	0	120	10.0	160
004	Female	Enrollment	15	100.0	5	0.5	7	0.0	0	0.0	0	75	7.5	105
		Week 1	10	100.0	5	0.5	7	0.0	0	0.0	0	50	5.0	70
		Week 2	11	100.0	5	0.5	7	0.0	0	0.0	0	55	5.5	77
		Week 3	12	100.0	5	0.5	7	0.0	0	0.0	0	60	6.0	84
		Week 6	12	100.0	5	0.5	7	0.0	0	0.0	0	60	6.0	84
005	Female	Enrollment	4	100.0	5	0.5	7	0.0	0	0.0	0	20	2.0	28
		Week 1	4	100.0	5	0.5	7	0.0	0	0.0	0	20	2.0	28
		Week 2	4	100.0	5	0.5	7	0.0	0	0.0	0	20	2.0	28
		Week 3	4	100.0	5	0.5	7	0.0	0	0.0	0	20	2.0	28
		Week 6	4	100.0	5	0.5	7	0.0	0	0.0	0	20	2.0	28
006	Female	Enrollment	20	99.0	6	0.5	8	1.0	6	0.5	7	120	10.0	160
		Week 1	20	100.0	6	0.5	8	0.0	0	0.0	0	120	10.0	160
		Week 2	20	100.0	6	0.5	8	0.0	0	0.0	0	120	10.0	160
		Week 3	20	100.0	6	0.5	8	0.0	0	0.0	0	120	10.0	160
		Week 6	20	100.0	6	0.5	8	0.0	0	0.0	0	120	10.0	160
007	Female	Enrollment	10	100.0	5	0.5	7	0.0	0	0.0	0	50	5.0	70
		Week 1	15	100.0	5	0.5	7	0.0	0	0.0	0	75	7.5	105
		Week 2	15	100.0	5	0.5	7	0.0	0	0.0	0	75	7.5	105
		Week 3	17	100.0	5	0.5	7	0.0	0	0.0	0	85	8.5	119
		Week 6	20	100.0	5	0.5	7	0.0	0	0.0	0	100	10.0	140

NOTE: TAR, NICOTINE, and CO FTC values gathered from 2000 Federal Trade Commission Report and from Sponsor information.

This listing excludes subject as presented in Listing 16.5-2.

^a Calculation for Totals is Total # of Cigarettes * Preferred Brand percentage of use * Preferred Brand FTC value + the sum of (Cigarettes per Day * Alternate Brand percentage of use * Alternate Brand FTC value)

Listing 16.6-3
Self-Exposed FTC Values for Smokers by Subject
(Page 2 of 9)

Subject Number	Gender	Timepoint	Cigarettes per Day	Percentage of Use	Preferred Brand			Percentage of Use	Alternate Brand(s)			Totals ^a		
					TAR (mg/cig)	NICOTINE (mg/cig)	CO (mg/cig)		TAR (mg/cig)	NICOTINE (mg/cig)	CO (mg/cig)	TAR (mg)	NICOTINE (mg)	CO (mg)
008	Female	Enrollment	20	100.0	4	0.3	7	0.0	0	0.0	0	80	6.0	140
		Week 1	22	100.0	4	0.3	7	0.0	0	0.0	0	88	6.6	154
		Week 2	20	100.0	4	0.3	7	0.0	0	0.0	0	80	6.0	140
		Week 3	20	100.0	4	0.3	7	0.0	0	0.0	0	80	6.0	140
		Week 6	20	100.0	4	0.3	7	0.0	0	0.0	0	80	6.0	140
009	Female	Enrollment	10	99.0	6	0.5	6	1.0	6	0.5	5	60	5.0	60
		Week 1	12	100.0	6	0.5	6	0.0	0	0.0	0	72	6.0	72
		Week 2	15	100.0	6	0.5	6	0.0	0	0.0	0	90	7.5	90
		Week 3	15	100.0	6	0.5	6	0.0	0	0.0	0	90	7.5	90
		Week 6	12	100.0	6	0.5	6	0.0	0	0.0	0	72	6.0	72
010	Female	Enrollment	5	95.0	6	0.5	8	5.0	6	0.5	7	30	2.5	40
		Week 1	3	100.0	6	0.5	8	0.0	0	0.0	0	18	1.5	24
		Week 2	5	100.0	6	0.5	8	0.0	0	0.0	0	30	2.5	40
011	Female	Enrollment	25	100.0	4	0.4	5	0.0	0	0.0	0	100	10.0	125
		Week 1	25	100.0	4	0.4	5	0.0	0	0.0	0	100	10.0	125
		Week 2	30	100.0	4	0.4	5	0.0	0	0.0	0	120	12.0	150
		Week 3	20	100.0	4	0.4	5	0.0	0	0.0	0	80	8.0	100
		Week 6	25	100.0	4	0.4	5	0.0	0	0.0	0	100	10.0	125
012	Female	Enrollment	30	100.0	6	0.5	8	0.0	0	0.0	0	180	15.0	240
		Week 1	22	100.0	6	0.5	8	0.0	0	0.0	0	132	11.0	176
		Week 2	21	100.0	6	0.5	8	0.0	0	0.0	0	126	10.5	168
		Week 3	21	100.0	6	0.5	8	0.0	0	0.0	0	126	10.5	168
		Week 6	22	100.0	6	0.5	8	0.0	0	0.0	0	132	11.0	176
013	Female	Enrollment	20	100.0	5	0.5	9	0.0	0	0.0	0	100	10.0	180
		Week 1	20	100.0	5	0.5	9	0.0	0	0.0	0	100	10.0	180
		Week 2	20	100.0	5	0.5	9	0.0	0	0.0	0	100	10.0	180
		Week 3	20	100.0	5	0.5	9	0.0	0	0.0	0	100	10.0	180
		Week 6	20	100.0	5	0.5	9	0.0	0	0.0	0	100	10.0	180

NOTE: TAR, NICOTINE, and CO FTC values gathered from 2000 Federal Trade Commission Report and from Sponsor information.

This listing excludes subject as presented in Listing 16.5.2.

^a Calculation for Totals is 'Total # of Cigarettes' * 'Preferred Brand percentage of use' * 'Preferred Brand FTC value' + the sum of ('Cigarettes per Day' * 'Alternate Brand percentage of use' * 'Alternate Brand FTC value')

Listing 16.6-3
Self-Exposed FTC Values for Smokers by Subject
(Page 3 of 9)

Subject Number	Gender	Timepoint	Cigarettes per Day	Percentage of Use	Preferred Brand			Percentage of Use	Alternate Brand(s)			Totals ^a		
					TAR (mg/cig)	NICOTINE (mg/cig)	CO (mg/cig)		TAR (mg/cig)	NICOTINE (mg/cig)	CO (mg/cig)	TAR (mg)	NICOTINE (mg)	CO (mg)
015	Female	Enrollment	3	100.0	6	0.5	7	0.0	0	0.0	0	18	1.5	21
		Week 1	3	100.0	6	0.5	7	0.0	0	0.0	0	18	1.5	21
		Week 2	3	100.0	6	0.5	7	0.0	0	0.0	0	18	1.5	21
		Week 3	5	100.0	6	0.5	7	0.0	0	0.0	0	30	2.5	35
		Week 6	2	100.0	6	0.5	7	0.0	0	0.0	0	12	1.0	14
016	Female	Enrollment	20	100.0	5	0.5	7	0.0	0	0.0	0	100	10.0	140
		Week 1	20	100.0	5	0.5	7	0.0	0	0.0	0	100	10.0	140
		Week 2	20	100.0	5	0.5	7	0.0	0	0.0	0	100	10.0	140
		Week 3	20	100.0	5	0.5	7	0.0	0	0.0	0	100	10.0	140
		Week 6	20	100.0	5	0.5	7	0.0	0	0.0	0	100	10.0	140
017	Female	Enrollment	20	100.0	5	0.5	7	0.0	0	0.0	0	100	10.0	140
019	Female	Enrollment	4	100.0	6	0.5	7	0.0	0	0.0	0	24	2.0	28
		Week 1	4	100.0	6	0.5	7	0.0	0	0.0	0	24	2.0	28
		Week 2	5	100.0	6	0.5	7	0.0	0	0.0	0	30	2.5	35
		Week 3	4	100.0	6	0.5	7	0.0	0	0.0	0	24	2.0	28
		Week 6	4	100.0	6	0.5	7	0.0	0	0.0	0	24	2.0	28
020	Female	Enrollment	30	98.0	5	0.5	5	2.0	6	0.5	7	151	15.0	151
		Week 1	30	100.0	5	0.5	5	0.0	0	0.0	0	150	15.0	150
		Week 2	30	100.0	5	0.5	5	0.0	0	0.0	0	150	15.0	150
		Week 3	30	100.0	5	0.5	5	0.0	0	0.0	0	150	15.0	150
		Week 6	30	100.0	5	0.5	5	0.0	0	0.0	0	150	15.0	150
022	Female	Enrollment	20	100.0	6	0.5	7	0.0	0	0.0	0	120	10.0	140
		Week 1	20	100.0	6	0.5	7	0.0	0	0.0	0	120	10.0	140
		Week 2	20	100.0	6	0.5	7	0.0	0	0.0	0	120	10.0	140
		Week 3	16	100.0	6	0.5	7	0.0	0	0.0	0	96	8.0	112
		Week 6	20	100.0	6	0.5	7	0.0	0	0.0	0	120	10.0	140

NOTE: TAR, NICOTINE, and CO FTC values gathered from 2000 Federal Trade Commission Report and from Sponsor information.

This listing excludes subject as presented in Listing 16.5-2.

^a Calculation for Totals is Total # of Cigarettes * Preferred Brand percentage of use * Preferred Brand FTC value + the sum of (Cigarettes per Day * Alternate Brand percentage of use * Alternate Brand FTC value)

Listing 16.6-3
Self-Exposed FTC Values for Smokers by Subject
(Page 4 of 9)

Subject Number	Gender	Timepoint	Cigarettes per Day	Percentage of Use	Preferred Brand			Percentage of Use	Alternate Brand(s)			TAR (mg)	Totals ^a	
					TAR (mg/cig)	NICOTINE (mg/cig)	CO (mg/cig)		TAR (mg/cig)	NICOTINE (mg/cig)	CO (mg/cig)		NICOTINE (mg)	CO (mg)
023	Female	Enrollment	10	100.0	6	0.5	8	0.0	0	0.0	0	60	5.0	80
		Week 1	10	100.0	6	0.5	8	0.0	0	0.0	0	60	5.0	80
		Week 2	9	100.0	6	0.5	8	0.0	0	0.0	0	54	4.5	72
		Week 3	8	100.0	6	0.5	8	0.0	0	0.0	0	48	4.0	64
		Week 6	7	100.0	6	0.5	8	0.0	0	0.0	0	42	3.5	56
024	Female	Enrollment	20	100.0	5	0.5	6	0.0	0	0.0	0	100	10.0	120
		Week 1	14	100.0	5	0.5	6	0.0	0	0.0	0	70	7.0	84
		Week 2	16	100.0	5	0.5	6	0.0	0	0.0	0	80	8.0	96
		Week 3	15	100.0	5	0.5	6	0.0	0	0.0	0	75	7.5	90
		Week 6	12	100.0	5	0.5	6	0.0	0	0.0	0	60	6.0	72
025	Female	Enrollment	5	100.0	5	0.5	9	0.0	0	0.0	0	25	2.5	45
		Week 1	12	100.0	5	0.5	9	0.0	0	0.0	0	60	6.0	108
		Week 2	10	100.0	5	0.5	9	0.0	0	0.0	0	50	5.0	90
		Week 3	9	100.0	5	0.5	9	0.0	0	0.0	0	45	4.5	81
		Week 6	20	100.0	5	0.5	9	0.0	0	0.0	0	100	10.0	180
026	Female	Enrollment	30	100.0	5	0.5	9	0.0	0	0.0	0	150	15.0	270
		Week 1	23	100.0	5	0.5	9	0.0	0	0.0	0	115	11.5	207
		Week 2	23	100.0	5	0.5	9	0.0	0	0.0	0	115	11.5	207
		Week 3	24	100.0	5	0.5	9	0.0	0	0.0	0	120	12.0	216
		Week 6	20	100.0	5	0.5	9	0.0	0	0.0	0	100	10.0	180
027	Female	Enrollment	15	100.0	5	0.5	6	0.0	0	0.0	0	75	7.5	90
		Week 1	15	100.0	5	0.5	6	0.0	0	0.0	0	75	7.5	90
		Week 2	17	100.0	5	0.5	6	0.0	0	0.0	0	85	8.5	102
		Week 3	16	100.0	5	0.5	6	0.0	0	0.0	0	80	8.0	96
		Week 6	12	100.0	5	0.5	6	0.0	0	0.0	0	60	6.0	72
028	Female	Enrollment	20	100.0	6	0.5	7	0.0	0	0.0	0	120	10.0	140
		Week 1	20	100.0	6	0.5	7	0.0	0	0.0	0	120	10.0	140
		Week 2	20	100.0	6	0.5	7	0.0	0	0.0	0	120	10.0	140
		Week 3	23	100.0	6	0.5	7	0.0	0	0.0	0	138	11.5	161
		Week 6	20	100.0	6	0.5	7	0.0	0	0.0	0	120	10.0	140

NOTE: TAR, NICOTINE, and CO FTC values gathered from 2000 Federal Trade Commission Report and from Sponsor information.
This listing excludes subject as presented in Listing 16.5-2.

^a Calculation for Totals is 'Total # of Cigarettes' * 'Preferred Brand percentage of use' * 'Preferred Brand FTC value' + the sum of ('Cigarettes per Day' * 'Alternate Brand percentage of use' * 'Alternate Brand FTC value')

Listing 16.6-3
Self-Exposed FTC Values for Smokers by Subject
(Page 5 of 9)

Subject Number	Gender	Timepoint	Cigarettes per Day	Percentage of Use	Preferred Brand			Percentage of Use	Alternate Brand(s)			Totals ^a		
					TAR (mg/cig)	NICOTINE (mg/cig)	CO (mg/cig)		TAR (mg/cig)	NICOTINE (mg/cig)	CO (mg/cig)	TAR (mg)	NICOTINE (mg)	CO (mg)
029	Female	Enrollment	20	100.0	6	0.5	8	0.0	0	0.0	0	120	10.0	160
		Week 1	15	100.0	6	0.5	8	0.0	0	0.0	0	90	7.5	120
		Week 2	15	100.0	6	0.5	8	0.0	0	0.0	0	90	7.5	120
		Week 3	15	100.0	6	0.5	8	0.0	0	0.0	0	90	7.5	120
		Week 6	15	100.0	6	0.5	8	0.0	0	0.0	0	90	7.5	120
030	Female	Enrollment	19	100.0	6	0.5	8	0.0	0	0.0	0	114	9.5	152
		Week 1	18	100.0	6	0.5	8	0.0	0	0.0	0	108	9.0	144
		Week 2	20	100.0	6	0.5	8	0.0	0	0.0	0	120	10.0	160
		Week 3	18	100.0	6	0.5	8	0.0	0	0.0	0	108	9.0	144
		Week 6	20	100.0	6	0.5	8	0.0	0	0.0	0	120	10.0	160
031	Female	Enrollment	4	100.0	6	0.5	7	0.0	0	0.0	0	24	2.0	28
		Week 1	5	100.0	6	0.5	7	0.0	0	0.0	0	30	2.5	35
		Week 2	3	100.0	6	0.5	7	0.0	0	0.0	0	18	1.5	21
032	Female	Enrollment	10	100.0	6	0.5	7	0.0	0	0.0	0	60	5.0	70
		Week 1	33	100.0	6	0.5	7	0.0	0	0.0	0	198	16.5	231
		Week 2	6	100.0	6	0.5	7	0.0	0	0.0	0	36	3.0	42
		Week 3	6	100.0	6	0.5	7	0.0	0	0.0	0	36	3.0	42
		Week 6	10	100.0	6	0.5	7	0.0	0	0.0	0	60	5.0	70
033	Female	Enrollment	20	100.0	6	0.5	8	0.0	0	0.0	0	120	10.0	160
		Week 1	15	100.0	6	0.5	8	0.0	0	0.0	0	90	7.5	120
		Week 2	10	100.0	6	0.5	8	0.0	0	0.0	0	60	5.0	80
		Week 3	20	100.0	6	0.5	8	0.0	0	0.0	0	120	10.0	160
034	Female	Enrollment	20	100.0	5	0.5	7	0.0	6	0.5	7	100	10.0	140
		Week 1	15	100.0	5	0.5	7	0.0	0	0.0	0	75	7.5	105
036	Male	Enrollment	18	100.0	6	0.5	7	0.0	0	0.0	0	108	9.0	126
		Week 1	18	100.0	6	0.5	7	0.0	0	0.0	0	108	9.0	126
		Week 2	15	100.0	6	0.5	7	0.0	0	0.0	0	90	7.5	105
		Week 3	15	100.0	6	0.5	7	0.0	0	0.0	0	90	7.5	105
		Week 6	18	100.0	6	0.5	7	0.0	0	0.0	0	108	9.0	126

NOTE: TAR, NICOTINE, and CO FTC values gathered from 2000 Federal Trade Commission Report and from Sponsor information.
This listing excludes subject as presented in Listing 16.5-2.

^a Calculation for Totals is 'Total # of Cigarettes' * 'Preferred Brand percentage of use' * 'Preferred Brand FTC value' + the sum of ('Cigarettes per Day' * 'Alternate Brand percentage of use' * 'Alternate Brand FTC value')

PM3006630463

Listing 16.6-3
Self-Exposed FTC Values for Smokers by Subject
(Page 6 of 9)

Subject Number	Gender	Timepoint	Cigarettes per Day	Percentage of Use	Preferred Brand			Percentage of Use	Alternate Brand(s)			Totals ^a		
					TAR (mg/cig)	NICOTINE (mg/cig)	CO (mg/cig)		TAR (mg/cig)	NICOTINE (mg/cig)	CO (mg/cig)	TAR (mg)	NICOTINE (mg)	CO (mg)
039	Male	Enrollment	40	100.0	6	0.5	8	0.0	0	0.0	0	240	20.0	320
		Week 1	40	100.0	6	0.5	8	0.0	0	0.0	0	240	20.0	320
		Week 2	40	100.0	6	0.5	8	0.0	0	0.0	0	240	20.0	320
		Week 3	40	100.0	6	0.5	8	0.0	0	0.0	0	240	20.0	320
		Week 6	40	100.0	6	0.5	8	0.0	0	0.0	0	240	20.0	320
041	Male	Enrollment	10	100.0	5	0.5	7	0.0	0	0.0	0	50	5.0	70
		Week 1	12	100.0	5	0.5	7	0.0	0	0.0	0	60	6.0	84
		Week 2	11	100.0	5	0.5	7	0.0	0	0.0	0	55	5.5	77
		Week 3	12	100.0	5	0.5	7	0.0	0	0.0	0	60	6.0	84
		Week 6	12	100.0	5	0.5	7	0.0	0	0.0	0	60	6.0	84
042	Male	Enrollment	20	100.0	5	0.5	7	0.0	0	0.0	0	100	10.0	140
		Week 1	11	100.0	5	0.5	7	0.0	0	0.0	0	55	5.5	77
		Week 2	14	100.0	5	0.5	7	0.0	0	0.0	0	70	7.0	98
		Week 3	15	100.0	5	0.5	7	0.0	0	0.0	0	75	7.5	105
		Week 6	19	100.0	5	0.5	7	0.0	0	0.0	0	95	9.5	133
045	Male	Enrollment	20	100.0	5	0.5	7	0.0	0	0.0	0	100	10.0	140
		Week 1	15	100.0	5	0.5	7	0.0	0	0.0	0	75	7.5	105
		Week 2	10	100.0	5	0.5	7	0.0	0	0.0	0	50	5.0	70
		Week 3	7	100.0	5	0.5	7	0.0	0	0.0	0	35	3.5	49
		Week 6	8	100.0	5	0.5	7	0.0	0	0.0	0	40	4.0	56
047	Male	Enrollment	15	100.0	6	0.5	7	0.0	0	0.0	0	90	7.5	105
		Week 1	7	100.0	6	0.5	7	0.0	0	0.0	0	42	3.5	49
		Week 2	7	100.0	6	0.5	7	0.0	0	0.0	0	42	3.5	49
		Week 3	7	100.0	6	0.5	7	0.0	0	0.0	0	42	3.5	49
050	Male	Enrollment	3	100.0	5	0.5	7	0.0	0	0.0	0	15	1.5	21
		Week 1	3	100.0	5	0.5	7	0.0	0	0.0	0	15	1.5	21
		Week 2	3	100.0	5	0.5	7	0.0	0	0.0	0	15	1.5	21
		Week 3	3	100.0	5	0.5	7	0.0	0	0.0	0	15	1.5	21
		Week 6	3	100.0	5	0.5	7	0.0	0	0.0	0	15	1.5	21

NOTE: TAR, NICOTINE, and CO FTC values gathered from 2000 Federal Trade Commission Report and from Sponsor information.

This listing excludes subject as presented in Listing 16.5-2.

^a Calculation for Totals is 'Total # of Cigarettes' * 'Preferred Brand percentage of use' * 'Preferred Brand FTC value' + the sum of ('Cigarettes per Day' * 'Alternate Brand percentage of use' * 'Alternate Brand FTC value')

PM3006630464

Listing 16.6-3
Self-Exposed FTC Values for Smokers by Subject
(Page 7 of 9)

Subject Number	Gender	Timepoint	Cigarettes per Day	Percentage of Use	Preferred Brand			Percentage of Use	Alternate Brand(s)			Totals ^a		
					TAR (mg/cig)	NICOTINE (mg/cig)	CO (mg/cig)		TAR (mg/cig)	NICOTINE (mg/cig)	CO (mg/cig)	TAR (mg)	NICOTINE (mg)	CO (mg)
052	Male	Enrollment	17	95.0	6	0.5	7	5.0	5	0.5	8	101	8.5	120
055	Male	Enrollment	30	100.0	5	0.5	7	0.0	10	0.7	13	150	15.0	210
		Week 1	23	100.0	5	0.5	7	0.0	0	0.0	0	115	11.5	161
		Week 2	20	100.0	5	0.5	7	0.0	0	0.0	0	100	10.0	140
056	Male	Enrollment	40	100.0	7	0.6	7	0.0	0	0.0	0	280	24.0	280
		Week 1	5	100.0	7	0.6	7	0.0	0	0.0	0	35	3.0	35
		Week 2	2	100.0	7	0.6	7	0.0	0	0.0	0	14	1.2	14
		Week 3	5	100.0	7	0.6	7	0.0	0	0.0	0	35	3.0	35
		Week 6	2	100.0	7	0.6	7	0.0	0	0.0	0	14	1.2	14
057	Male	Enrollment	18	100.0	6	0.5	7	0.0	9	0.7	11	108	9.0	126
		Week 1	18	100.0	6	0.5	7	0.0	0	0.0	0	108	9.0	126
		Week 2	18	100.0	6	0.5	7	0.0	0	0.0	0	108	9.0	126
		Week 3	18	100.0	6	0.5	7	0.0	0	0.0	0	108	9.0	126
		Week 6	20	100.0	6	0.5	7	0.0	0	0.0	0	120	10.0	140
058	Male	Enrollment	10	100.0	6	0.5	7	0.0	0	0.0	0	60	5.0	70
		Week 1	6	100.0	6	0.5	7	0.0	0	0.0	0	36	3.0	42
		Week 2	10	100.0	6	0.5	7	0.0	0	0.0	0	60	5.0	70
		Week 3	6	100.0	6	0.5	7	0.0	0	0.0	0	36	3.0	42
		Week 6	10	100.0	6	0.5	7	0.0	0	0.0	0	60	5.0	70
059	Male	Enrollment	22	100.0	6	0.6	8	0.0	0	0.0	0	132	13.2	176
		Week 1	20	100.0	6	0.6	8	0.0	0	0.0	0	120	12.0	160
		Week 2	22	100.0	6	0.6	8	0.0	0	0.0	0	132	13.2	176
		Week 3	18	100.0	6	0.6	8	0.0	0	0.0	0	108	10.8	144
		Week 6	22	100.0	6	0.6	8	0.0	0	0.0	0	132	13.2	176
060	Male	Enrollment	20	100.0	6	0.5	8	0.0	0	0.0	0	120	10.0	160
		Week 1	17	100.0	6	0.5	8	0.0	0	0.0	0	102	8.5	136
		Week 2	16	100.0	6	0.5	8	0.0	0	0.0	0	96	8.0	128
		Week 3	17	100.0	6	0.5	8	0.0	0	0.0	0	102	8.5	136
		Week 6	15	100.0	6	0.5	8	0.0	0	0.0	0	90	7.5	120

NOTE: TAR, NICOTINE, and CO FTC values gathered from 2000 Federal Trade Commission Report and from Sponsor information.

This listing excludes subject as presented in Listing 16.5-2.

^a Calculation for Totals is 'Total # of Cigarettes' * 'Preferred Brand percentage of use' * 'Preferred Brand FTC value' + the sum of ('Cigarettes per Day' * 'Alternate Brand percentage of use' * 'Alternate Brand FTC value')

Listing 16.6-3
Self-Exposed FTC Values for Smokers by Subject
(Page 8 of 9)

Subject Number	Gender	Timepoint	Cigarettes per Day	Percentage of Use	Preferred Brand			Percentage of Use	Alternate Brand(s)			Totals ^a		
					TAR (mg/cig)	NICOTINE (mg/cig)	CO (mg/cig)		TAR (mg/cig)	NICOTINE (mg/cig)	CO (mg/cig)	TAR (mg)	NICOTINE (mg)	CO (mg)
061	Male	Enrollment	15	100.0	6	0.5	7	0.0	0	0.0	0	90	7.5	105
		Week 1	16	100.0	6	0.5	7	0.0	0	0.0	0	96	8.0	112
		Week 2	15	100.0	6	0.5	7	0.0	0	0.0	0	90	7.5	105
		Week 3	6	100.0	6	0.5	7	0.0	0	0.0	0	36	3.0	42
062	Male	Enrollment	20	100.0	6	0.5	7	0.0	11	0.8	12	120	10.0	140
		Week 1	30	100.0	6	0.5	7	0.0	0	0.0	0	180	15.0	210
		Week 2	30	100.0	6	0.5	7	0.0	0	0.0	0	180	15.0	210
		Week 3	30	100.0	6	0.5	7	0.0	0	0.0	0	180	15.0	210
		Week 6	30	100.0	6	0.5	7	0.0	0	0.0	0	180	15.0	210
063	Male	Enrollment	20	100.0	6	0.5	7	0.0	0	0.0	0	120	10.0	140
		Week 1	6	100.0	6	0.5	7	0.0	0	0.0	0	36	3.0	42
		Week 2	15	100.0	6	0.5	7	0.0	0	0.0	0	90	7.5	105
		Week 3	6	100.0	6	0.5	7	0.0	0	0.0	0	36	3.0	42
		Week 6	14	100.0	6	0.5	7	0.0	0	0.0	0	84	7.0	98
065	Male	Enrollment	10	100.0	6	0.5	7	0.0	0	0.0	0	60	5.0	70
		Week 1	10	100.0	6	0.5	7	0.0	0	0.0	0	60	5.0	70
		Week 2	10	100.0	6	0.5	7	0.0	0	0.0	0	60	5.0	70
		Week 3	10	100.0	6	0.5	7	0.0	0	0.0	0	60	5.0	70
068	Male	Enrollment	20	100.0	6	0.5	7	0.0	0	0.0	0	120	10.0	140
069	Male	Enrollment	25	100.0	5	0.5	7	0.0	17	1.0	17	125	12.5	175
		Week 1	20	100.0	5	0.5	7	0.0	0	0.0	0	100	10.0	140
		Week 2	20	100.0	5	0.5	7	0.0	0	0.0	0	100	10.0	140
		Week 3	10	100.0	5	0.5	7	0.0	0	0.0	0	50	5.0	70
		Week 6	15	100.0	5	0.5	7	0.0	0	0.0	0	75	7.5	105
503	Female	Enrollment	20	100.0	6	0.5	7	0.0	0	0.0	0	120	10.0	140
		Week 1	20	100.0	6	0.5	7	0.0	0	0.0	0	120	10.0	140
		Week 2	20	100.0	6	0.5	7	0.0	0	0.0	0	120	10.0	140
		Week 3	16	100.0	6	0.5	7	0.0	0	0.0	0	96	8.0	112
		Week 6	16	100.0	6	0.5	7	0.0	0	0.0	0	96	8.0	112

NOTE: TAR, NICOTINE, and CO FTC values gathered from 2000 Federal Trade Commission Report and from Sponsor information.

This listing excludes subject as presented in Listing 16.5-2.

^a Calculation for Totals is 'Total # of Cigarettes' * 'Preferred Brand percentage of use' * 'Preferred Brand FTC value' + the sum of ('Cigarettes per Day' * 'Alternate Brand percentage of use' * 'Alternate Brand FTC value')

Listing 16.6-3
Self-Exposed FTC Values for Smokers by Subject
(Page 9 of 9)

Subject Number	Gender	Timepoint	Cigarettes per Day	Percentage of Use	Preferred Brand			Percentage of Use	Alternate Brand(s)			Totals ^a		
					TAR (mg/cig)	NICOTINE (mg/cig)	CO (mg/cig)		TAR (mg/cig)	NICOTINE (mg/cig)	CO (mg/cig)	TAR (mg)	NICOTINE (mg)	CO (mg)
504	Female	Enrollment	30	95.0	5	0.5	6	5.0	5	0.5	9	136	13.6	187
		Week 1	28	100.0	5	0.5	6	0.0	0	0.0	0	126	12.6	171
		Week 2	30	100.0	5	0.5	6	0.0	0	0.0	0	135	13.5	183
		Week 3	30	100.0	5	0.5	6	0.0	0	0.0	0	135	13.5	183
		Week 6	30	100.0	5	0.5	6	0.0	0	0.0	0	135	13.5	183
506	Female	Enrollment	3	100.0	6	0.6	8	0.0	0	0.0	0	18	1.8	24
		Week 1	2	100.0	6	0.6	8	0.0	0	0.0	0	12	1.2	16
		Week 2	1	100.0	6	0.6	8	0.0	0	0.0	0	6	0.6	8
		Week 3	4	100.0	6	0.6	8	0.0	0	0.0	0	24	2.4	32
		Week 6	3	100.0	6	0.6	8	0.0	0	0.0	0	18	1.8	24

NOTE: TAR, NICOTINE, and CO FTC values gathered from 2000 Federal Trade Commission Report and from Sponsor information.
This listing excludes subject as presented in Listing 16.5-2.

^a Calculation for Totals is 'Total # of Cigarettes' * 'Preferred Brand percentage of use' * 'Preferred Brand FTC value' + the sum of ('Cigarettes per Day' * 'Alternate Brand percentage of use' * 'Alternate Brand FTC value')

Listing 16.6-4
Nicotine from Cigarette Filters by Subject
(Page 1 of 10)

Subject Number	Gender	Timepoint	Filter 1 (mg/filter)	Filter 2 (mg/filter)	Filter 3 (mg/filter)	Filter 4 (mg/filter)	Filter 5 (mg/filter)	Filter 6 (mg/filter)	Filter 7 (mg/filter)	Filter 8 (mg/filter)	Filter 9 (mg/filter)	Filter 10 (mg/filter)
001	Female	Week 1	1.10	0.84	1.00	0.78	1.06	0.94	1.17	1.37	1.16	1.18
		Week 2	0.60	0.67	0.75	0.69	0.56	0.75	0.46	0.79	0.85	0.60
		Week 3	1.00	0.77	0.61	0.75	0.77	0.83	0.44	0.66	0.97	0.84
		Week 6	0.70	0.66	0.50	0.70	0.81	0.68	0.70	0.65	0.53	0.71
002	Female	Week 1	1.10	1.00	0.80	0.95	1.23	0.94	0.87	1.14	1.38	1.37
		Week 2	1.20	1.32	1.02	0.98	1.17	0.91	1.54	1.19	1.28	0.96
		Week 3	0.70	1.14	0.90	0.75	0.99	0.87	0.68	0.89	1.22	0.93
		Week 6	0.80	0.59	0.99	1.09	1.16	0.95	0.87	1.06	0.82	0.75
003	Female	Week 1	0.30	0.28	0.37	0.28	0.45	0.49	0.36	0.23	0.39	0.53
		Week 2	0.30	0.27	0.31	0.60	0.27	0.29	0.37	0.35	0.32	0.36
		Week 3	0.30	0.30	0.44	0.34	0.52	0.41	0.36	0.29	0.30	0.38
		Week 6	0.20	0.29	0.25	0.39	0.28	0.81	0.25	0.40	0.47	0.66
004	Female	Week 1	0.60	0.62	0.72	0.78	0.82	0.72	0.56	0.75	0.91	0.78
		Week 2	0.90	0.79	0.69	0.75	0.49	0.74	0.46	0.87	0.79	1.00
		Week 3	0.70	0.48	0.59	0.68	0.75	0.68	0.85	0.89	0.74	0.83
		Week 6	0.70	0.90	0.64	0.89	0.76	0.54	0.75	0.63	0.65	0.80
005	Female	Week 1	1.30	0.75	0.74	0.70	0.58	1.05	0.69	0.73	0.79	0.85
		Week 2	0.50	0.62	0.66	0.67	0.56	0.53	0.75	0.51	0.64	1.09
		Week 3	0.70	0.93	0.87	0.54	0.61	0.51	0.76	1.12	0.87	0.67
		Week 6	0.30	0.34	0.39	0.27	0.29	0.32	0.41	0.52	0.33	0.33
006	Female	Week 1	1.10	0.89	0.66	0.72	0.64	1.01	1.06	0.72	0.57	0.84
		Week 2	0.60	0.71	0.70	1.10	0.82	0.68	0.84	0.63	0.90	0.70
		Week 3	0.90	0.67	1.03	1.19	0.88	0.99	0.86	0.76	0.73	0.74
		Week 6	0.50	0.70	1.01	0.63	0.58	0.81	0.68	0.70	0.83	0.76
007	Female	Week 1	0.40	0.50	0.57	0.43	0.60	0.91	0.67	0.70	0.83	0.87
		Week 2	0.50	0.52	0.43	0.54	0.62	0.42	0.54	0.52	0.51	0.53
		Week 3	0.40	0.54	0.59	0.49	0.44	0.49	0.41	0.42	0.38	0.70
		Week 6	0.50	0.61	0.59	0.62	0.53	0.67	0.55	0.71	0.77	0.64

NOTE: QNS' - Quantity not sufficient., NSR' - No specimen received.

Listing 16.6-4
Nicotine from Cigarette Filters by Subject
(Page 2 of 10)

Subject Number	Gender	Timepoint	Filter 1 (mg/filter)	Filter 2 (mg/filter)	Filter 3 (mg/filter)	Filter 4 (mg/filter)	Filter 5 (mg/filter)	Filter 6 (mg/filter)	Filter 7 (mg/filter)	Filter 8 (mg/filter)	Filter 9 (mg/filter)	Filter 10 (mg/filter)
008	Female	Week 1	0.60	0.47	0.66	0.64	0.60	0.47	0.65	0.91	0.50	0.36
		Week 2	0.40	0.46	0.48	0.50	0.55	0.43	0.61	0.56	0.46	0.48
		Week 3	0.50	0.66	0.58	0.57	0.47	0.45	0.29	0.58	0.41	0.53
		Week 6	0.40	0.37	0.49	0.45	0.38	0.43	0.44	0.32	0.36	0.43
009	Female	Week 1	0.70	0.83	0.81	0.69	0.77	0.79	0.84	0.83	0.68	0.80
		Week 2	0.70	0.68	0.62	0.72	0.88	0.70	0.77	0.58	0.48	0.72
		Week 3	0.50	0.70	0.72	0.57	0.66	0.66	0.76	0.73	0.68	0.55
		Week 6	0.60	0.70	0.59	0.65	0.75	0.69	0.58	0.67	0.83	0.90
010	Female	Week 1	0.50	0.81	0.77	0.31	0.77	0.47	0.94	0.95	QNS	QNS
		Week 2	0.60	1.05	0.99	0.94	1.05	1.12	1.01	0.93	1.28	0.83
011	Female	Week 1	0.40	0.56	0.37	0.51	0.51	0.38	0.41	0.40	0.42	0.44
		Week 2	0.30	0.37	0.43	0.39	0.39	0.39	0.33	0.43	0.38	0.42
		Week 3	0.40	0.35	0.29	0.25	0.62	0.40	0.31	0.34	0.36	0.34
		Week 6	0.30	0.35	0.34	0.27	0.61	0.29	0.40	0.38	0.42	0.47
012	Female	Week 1	0.70	0.73	0.61	0.62	0.84	0.69	0.68	0.63	0.65	0.80
		Week 2	0.60	0.63	0.75	0.64	0.64	0.68	0.66	0.67	0.74	0.57
		Week 3	0.50	0.60	0.72	0.84	0.68	0.72	0.82	0.62	0.49	0.78
		Week 6	0.60	0.80	0.60	0.65	0.56	0.56	0.70	0.87	0.84	0.70
013	Female	Week 1	0.80	0.77	0.82	0.89	0.75	0.84	0.90	0.79	0.71	0.78
		Week 2	0.70	0.90	0.67	0.83	0.77	0.80	0.94	0.64	0.80	0.73
		Week 3	0.80	0.75	1.00	0.52	0.76	0.61	0.81	0.72	0.60	0.80
		Week 6	0.80	0.62	0.64	0.54	0.82	0.50	0.79	0.72	0.71	0.85
014	Female	Week 1	1.80	1.85	2.02	2.00	2.02	1.93	2.18	1.37	2.29	2.33
		Week 2	1.50	1.56	1.45	1.95	1.70	1.74	1.44	1.69	1.95	1.98
		Week 3	1.90	1.72	1.95	1.41	1.82	1.84	1.80	1.80	1.99	2.19
		Week 6	1.80	1.73	1.72	1.49	1.88	1.78	1.90	1.77	1.97	2.02

NOTE: QNS = Quantity not sufficient, NSR = No specimen received.

Listing 16.6-4
Nicotine from Cigarette Filters by Subject
(Page 3 of 10)

Subject Number	Gender	Timepoint	Filter 1 (mg/filter)	Filter 2 (mg/filter)	Filter 3 (mg/filter)	Filter 4 (mg/filter)	Filter 5 (mg/filter)	Filter 6 (mg/filter)	Filter 7 (mg/filter)	Filter 8 (mg/filter)	Filter 9 (mg/filter)	Filter 10 (mg/filter)
015	Female	Week 1	1.10	1.63	1.17	0.98	1.08	1.02	0.97	1.05	0.92	QNS
		Week 2	1.30	0.68	1.01	0.95	1.06	QNS	QNS	QNS	QNS	QNS
		Week 3	0.80	1.06	0.93	1.35	1.11	0.99	0.90	1.12	0.92	1.29
		Week 6	0.60	0.56	0.51	0.67	0.68	0.62	0.48	0.54	0.52	0.80
016	Female	Week 1	0.70	0.90	0.75	0.79	0.60	0.53	0.90	0.56	0.56	0.70
		Week 2	0.70	0.76	0.72	0.63	0.85	0.79	0.61	0.74	0.81	0.92
		Week 3	0.70	0.80	0.71	0.71	0.67	0.61	0.93	0.73	0.74	0.74
		Week 6	0.60	0.68	0.72	0.74	0.58	0.67	0.79	0.60	0.47	0.60
017	Female	Week 1	0.70	0.75	0.75	0.63	0.83	0.70	0.89	0.70	0.64	0.73
		Week 2	0.80	0.81	0.73	0.82	0.71	0.92	0.75	0.68	0.74	0.75
		Week 3	0.70	0.71	0.82	0.85	0.77	0.67	0.72	0.75	0.86	0.78
		Week 6	0.60	0.75	0.65	0.80	0.76	0.74	0.70	0.64	0.63	0.74
018	Female	Week 1	0.40	0.45	0.53	0.49	0.40	0.41	0.63	0.53	0.56	0.44
		Week 2	0.60	0.44	0.58	0.52	0.39	0.47	0.50	0.40	0.53	0.82
		Week 3	0.60	0.45	0.52	0.53	0.49	0.63	0.62	0.50	0.48	0.47
		Week 6	0.40	0.42	0.51	0.55	0.72	0.66	0.37	0.56	0.53	0.48
019	Female	Week 1	0.60	0.66	0.49	0.58	0.62	0.78	0.60	0.73	0.62	0.79
		Week 2	0.60	0.83	0.65	0.60	0.60	0.75	0.69	0.66	0.63	0.60
		Week 3	0.80	0.84	0.76	0.64	0.78	0.72	0.72	0.79	0.84	0.90
		Week 6	0.70	0.80	0.70	0.60	0.79	0.87	0.58	0.72	0.59	0.70
020	Female	Week 1	0.30	0.87	0.33	0.55	0.75	0.68	0.48	0.59	0.79	1.08
		Week 2	0.70	0.58	0.86	0.78	0.60	0.63	0.58	0.43	0.55	0.63
		Week 3	0.80	0.81	0.69	0.84	0.38	0.73	0.65	0.53	0.56	0.47
		Week 6	0.50	0.52	0.61	0.43	0.43	0.45	0.45	0.49	0.51	0.36
021	Female	Week 1	0.50	0.51	0.52	0.48	0.68	0.40	0.67	0.52	0.65	0.62
		Week 2	0.50	0.50	0.56	0.49	0.51	0.59	0.60	0.55	0.62	0.46
		Week 3	0.40	0.50	0.34	0.45	0.44	0.36	0.52	0.70	0.49	0.59
		Week 6	0.50	0.40	0.84	0.66	0.76	0.59	0.34	0.63	0.53	0.59

NOTE: QNS = Quantity not sufficient, NSR = No specimen received.

Listing 16.6-4
Nicotine from Cigarette Filters by Subject
(Page 4 of 10)

Subject Number	Gender	Timepoint	Filter 1 (mg/filter)	Filter 2 (mg/filter)	Filter 3 (mg/filter)	Filter 4 (mg/filter)	Filter 5 (mg/filter)	Filter 6 (mg/filter)	Filter 7 (mg/filter)	Filter 8 (mg/filter)	Filter 9 (mg/filter)	Filter 10 (mg/filter)
022	Female	Week 1	0.70	0.69	0.80	0.83	0.88	0.84	0.96	0.87	0.78	1.06
		Week 2	0.90	1.02	1.13	1.08	0.83	0.88	0.82	0.89	1.01	0.80
		Week 3	1.10	1.21	0.95	1.47	0.66	1.00	0.83	0.94	1.01	0.99
		Week 6	0.90	0.79	1.06	0.93	0.81	0.72	0.75	0.63	1.11	0.98
023	Female	Week 1	1.30	1.30	1.13	0.94	0.63	1.35	1.72	1.26	0.74	1.31
		Week 2	1.30	1.15	1.59	1.36	1.04	0.95	1.11	1.02	1.35	1.22
		Week 3	0.90	0.90	1.10	0.87	0.79	0.84	0.82	0.71	0.86	0.95
		Week 6	1.30	1.80	0.91	1.19	1.14	1.19	1.22	1.09	1.67	1.19
024	Female	Week 1	0.70	0.87	0.67	0.73	0.77	0.69	0.94	0.77	0.63	0.52
		Week 2	0.60	0.78	0.61	0.76	0.56	0.64	0.81	0.62	0.72	1.00
		Week 3	0.70	0.78	0.73	0.68	0.59	0.64	0.81	0.94	0.61	0.78
		Week 6	1.10	0.80	0.82	0.89	0.70	0.79	0.70	1.03	0.92	0.84
025	Female	Week 1	0.70	0.88	0.70	0.79	0.67	1.02	0.88	0.98	0.90	0.80
		Week 2	0.10	0.54	0.34	0.58	0.14	0.21	0.44	0.37	0.17	0.38
		Week 3	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR
		Week 6	0.80	0.83	0.47	0.83	0.78	0.66	1.12	1.17	0.85	0.89
026	Female	Week 1	0.70	0.81	0.80	0.96	0.89	0.79	0.95	0.74	0.79	0.74
		Week 2	0.80	0.86	0.75	0.52	0.78	1.05	0.71	0.78	0.62	0.87
		Week 3	1.30	0.83	0.98	0.98	0.98	0.99	0.94	1.21	0.88	1.08
		Week 6	0.90	0.76	1.04	0.81	0.65	0.75	1.19	0.97	0.93	1.31
027	Female	Week 1	0.90	1.08	1.04	0.84	0.77	1.00	0.83	0.88	0.91	0.84
		Week 2	0.90	0.86	1.13	0.78	0.92	0.94	0.82	1.06	0.83	0.96
		Week 3	0.80	1.22	0.85	1.20	0.97	1.00	1.02	1.06	1.33	0.83
		Week 6	0.90	0.83	1.01	0.82	0.90	0.91	0.78	1.14	0.81	0.78
028	Female	Week 1	0.70	0.77	0.59	0.85	0.82	0.93	1.34	0.68	1.25	1.03
		Week 2	0.60	0.65	0.72	0.66	0.52	0.71	0.59	0.59	0.73	0.59
		Week 3	0.50	0.44	0.66	0.70	0.72	0.65	0.64	1.03	0.73	0.68
		Week 6	0.50	0.54	0.62	0.42	0.53	0.76	0.51	0.78	0.57	0.56

NOTE: QNS = Quantity not sufficient, NSR = No specimen received.

Listing 16.6-4
Nicotine from Cigarette Filters by Subject
(Page 5 of 10)

Subject Number	Gender	Timepoint	Filter 1 (mg/filter)	Filter 2 (mg/filter)	Filter 3 (mg/filter)	Filter 4 (mg/filter)	Filter 5 (mg/filter)	Filter 6 (mg/filter)	Filter 7 (mg/filter)	Filter 8 (mg/filter)	Filter 9 (mg/filter)	Filter 10 (mg/filter)
029	Female	Week 1	0.70	0.74	0.84	0.58	0.51	0.60	0.57	0.67	0.48	0.81
		Week 2	0.60	0.84	0.55	0.60	0.94	0.54	0.72	0.82	0.62	0.85
		Week 3	0.50	0.76	0.51	0.45	0.61	0.44	0.62	0.73	0.53	0.66
		Week 6	0.70	0.69	0.76	0.62	0.72	0.57	0.59	0.52	0.78	0.60
030	Female	Week 1	0.70	0.65	0.65	0.81	0.79	0.79	QNS	QNS	QNS	QNS
		Week 2	0.80	0.66	0.81	0.77	1.14	0.98	0.73	0.69	0.90	1.12
		Week 3	1.10	0.74	0.80	1.07	0.68	0.88	0.71	1.39	0.45	0.67
		Week 6	0.90	0.84	0.80	0.73	0.64	1.10	0.62	0.61	0.60	0.74
031	Female	Week 1	0.50	0.66	0.65	0.63	0.55	0.58	0.79	0.62	0.67	0.72
		Week 2	0.70	0.78	0.72	0.64	0.69	0.74	0.72	0.81	0.84	0.37
		Week 3	0.50	0.46	0.49	0.49	0.74	QNS	QNS	QNS	QNS	QNS
		Week 6	0.50	0.53	QNS	QNS	QNS	QNS	QNS	QNS	QNS	QNS
032	Female	Week 1	0.90	0.79	0.85	1.27	0.90	0.66	1.15	1.06	1.00	1.01
		Week 2	0.80	1.10	1.06	1.17	1.16	0.91	1.13	1.05	1.10	0.94
		Week 3	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR
		Week 6	0.90	0.94	1.17	1.25	1.01	0.83	1.03	0.94	0.67	1.05
033	Female	Week 1	0.30	0.20	0.38	0.23	0.24	0.32	0.28	0.21	0.17	0.28
		Week 2	0.10	0.21	0.36	0.23	0.25	0.28	0.23	0.15	0.28	0.23
		Week 3	0.30	0.36	0.31	0.36	0.30	0.26	0.27	0.26	0.24	0.36
		Week 6	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR
034	Female	Week 1	0.40	0.44	0.43	0.63	0.31	0.48	0.50	0.52	0.50	0.55
		Week 2	0.50	0.47	0.46	0.44	0.73	0.70	0.21	0.42	0.34	0.45
		Week 3	0.80	0.62	0.63	0.65	0.52	0.80	0.80	0.71	0.80	0.67
		Week 6	0.40	0.22	0.40	0.40	0.22	0.44	0.47	0.29	0.37	0.48
035	Female	Week 1	0.50	0.67	0.56	0.61	0.56	0.55	0.66	0.61	0.82	0.63
		Week 2	0.50	0.47	0.65	0.37	0.50	0.55	0.67	0.54	0.52	0.52
		Week 3	0.30	0.49	0.71	0.50	0.35	0.63	0.50	0.46	0.51	0.49
		Week 6	0.40	0.62	0.62	0.35	0.40	0.65	0.58	0.46	0.50	0.56

NOTE: QNS=Quantity not sufficient, NSR=No specimen received.

Listing 16.6-4
Nicotine from Cigarette Filters by Subject
(Page 6 of 10)

Subject Number	Gender	Timepoint	Filter 1 (mg/filter)	Filter 2 (mg/filter)	Filter 3 (mg/filter)	Filter 4 (mg/filter)	Filter 5 (mg/filter)	Filter 6 (mg/filter)	Filter 7 (mg/filter)	Filter 8 (mg/filter)	Filter 9 (mg/filter)	Filter 10 (mg/filter)
036	Male	Week 1	0.90	1.00	0.85	0.92	0.86	0.89	1.10	1.14	0.98	1.20
		Week 2	1.00	1.05	0.99	0.91	1.02	0.89	0.86	0.93	0.95	0.88
		Week 3	1.00	1.07	0.96	0.81	1.02	1.06	0.86	0.89	1.06	0.98
		Week 6	1.00	0.88	1.04	0.92	0.86	0.90	1.06	0.93	1.12	0.94
037	Male	Week 1	2.00	1.68	1.97	1.47	2.12	1.58	1.97	2.32	1.93	1.87
		Week 2	2.10	2.06	2.39	1.98	1.89	1.88	2.20	1.96	2.05	2.33
		Week 3	1.80	1.80	2.08	1.40	2.15	2.00	1.38	1.91	1.81	1.56
		Week 6	1.50	1.74	1.77	1.70	1.60	1.76	2.11	1.58	1.63	1.86
038	Male	Week 1	0.70	1.19	1.01	0.74	1.00	1.26	0.71	1.01	0.78	0.85
		Week 2	0.70	0.59	0.71	0.77	0.73	0.60	0.87	0.74	0.60	0.86
		Week 3	0.80	0.84	0.69	0.83	0.67	0.95	0.67	0.78	0.91	0.83
		Week 6	0.10	0.30	0.20	0.15	0.12	0.26	0.27	0.19	0.13	0.29
039	Male	Week 1	1.50	1.26	0.96	1.32	1.11	1.04	0.85	1.00	1.19	1.41
		Week 2	1.00	0.98	0.72	0.68	1.10	0.92	0.91	0.98	0.58	1.06
		Week 3	0.90	0.82	1.03	0.99	0.74	0.89	1.01	1.20	0.97	1.37
		Week 6	0.90	0.92	1.09	1.11	0.94	1.39	1.05	1.17	1.19	1.12
040	Male	Week 1	0.30	0.25	0.18	0.27	0.29	0.28	0.21	0.23	0.32	0.24
		Week 2	0.10	0.09	0.14	0.11	0.12	0.12	0.07	0.13	0.14	0.39
		Week 3	0.60	0.83	0.66	0.96	0.84	1.00	0.92	0.87	0.78	0.86
		Week 6	0.10	0.14	0.16	0.28	0.04	0.17	0.22	0.22	0.07	0.20
041	Male	Week 1	1.00	1.04	1.19	1.04	0.79	1.17	1.03	0.85	1.06	0.92
		Week 2	0.90	0.83	1.08	1.00	0.87	0.74	1.20	0.70	0.91	0.79
		Week 3	1.10	0.88	0.88	0.97	1.20	0.82	0.74	0.85	0.83	0.88
		Week 6	0.70	0.91	0.78	0.90	0.78	0.65	0.45	0.95	0.93	0.79
042	Male	Week 1	1.10	1.81	1.43	1.38	1.48	1.14	1.54	1.38	1.51	1.36
		Week 2	1.20	1.36	1.24	1.13	1.36	1.58	1.36	0.52	3.06	1.41
		Week 3	1.10	1.27	1.14	1.35	1.16	1.04	1.18	1.09	1.05	1.00
		Week 6	1.10	1.23	1.23	1.53	1.29	1.40	1.23	1.18	1.35	1.44

NOTE: QNS'= Quantity not sufficient, NSR'= No specimen received.

Listing 16.6-4
Nicotine from Cigarette Filters by Subject
(Page 7 of 10)

Subject Number	Gender	Timepoint	Filter 1 (mg/filter)	Filter 2 (mg/filter)	Filter 3 (mg/filter)	Filter 4 (mg/filter)	Filter 5 (mg/filter)	Filter 6 (mg/filter)	Filter 7 (mg/filter)	Filter 8 (mg/filter)	Filter 9 (mg/filter)	Filter 10 (mg/filter)
043	Male	Week 1	1.00	0.82	0.58	0.88	0.84	0.79	0.73	1.00	0.95	0.68
		Week 2	0.50	0.52	0.89	0.71	0.65	0.70	0.79	0.76	0.68	0.72
		Week 3	0.70	0.63	0.84	0.63	0.87	0.91	0.89	0.87	0.62	0.83
		Week 6	0.60	0.60	0.67	0.59	1.05	0.56	0.63	0.63	0.74	0.53
044	Male	Week 1	0.70	0.81	0.76	0.88	0.92	0.85	0.84	0.86	0.83	0.84
		Week 2	0.70	0.64	0.78	0.71	0.80	0.69	0.62	0.74	0.90	0.81
		Week 3	0.70	0.66	0.68	0.78	0.66	0.79	0.68	0.72	0.61	0.68
		Week 6	0.60	0.65	0.63	0.59	0.58	0.58	0.71	0.67	0.60	0.76
045	Male	Week 1	0.70	0.62	0.65	0.77	0.65	0.80	0.84	0.66	0.79	0.63
		Week 2	0.70	0.95	0.77	0.61	0.81	0.77	0.80	0.82	0.85	0.63
		Week 3	0.70	0.70	0.70	0.72	1.23	0.70	0.68	0.77	0.60	0.76
		Week 6	0.60	0.73	0.58	0.68	0.68	0.93	0.57	0.73	1.13	0.47
046	Male	Week 1	1.10	0.89	0.83	0.94	1.05	1.04	0.93	0.99	0.62	1.26
		Week 2	0.90	0.96	0.75	0.78	0.67	0.71	0.69	0.85	0.67	0.86
		Week 3	0.80	0.73	0.92	0.75	0.74	0.87	0.92	0.89	0.76	1.03
		Week 6	0.70	1.02	0.64	0.71	0.80	0.74	0.65	0.76	0.78	0.58
047	Male	Week 1	0.70	0.75	0.72	0.64	0.96	0.51	0.84	0.78	0.71	0.77
		Week 2	0.80	0.91	0.70	0.81	0.80	0.74	0.68	0.62	0.60	0.74
		Week 3	0.60	0.96	0.71	1.01	0.79	0.88	0.80	0.80	0.83	0.74
		Week 6	0.60	0.56	0.62	0.59	0.69	0.71	0.70	0.66	0.63	0.64
048	Male	Week 1	0.90	0.72	0.74	0.83	0.84	0.64	0.68	0.78	0.66	0.58
		Week 2	0.70	0.76	0.89	0.98	0.96	0.87	0.86	0.87	0.87	1.01
		Week 3	0.80	0.84	0.72	0.72	0.97	0.83	0.90	1.01	0.90	1.00
		Week 6	0.70	0.97	0.89	0.89	0.91	0.85	0.90	0.82	0.77	0.98
049	Male	Week 1	1.00	1.27	1.28	1.09	1.19	1.22	1.03	1.37	1.16	1.24
		Week 2	1.20	1.20	1.19	1.50	1.22	1.31	1.21	1.34	1.14	1.07
		Week 3	1.40	1.34	1.10	1.07	0.99	1.26	0.83	1.43	1.10	0.93
		Week 6	2.40	1.08	0.91	2.17	1.88	1.11	0.96	0.92	2.09	0.69

NOTE: QNS' = Quantity not sufficient., NSR' = No specimen received.

Listing 16.6-4
Nicotine from Cigarette Filters by Subject
(Page 8 of 10)

Subject Number	Gender	Timepoint	Filter 1 (mg/filter)	Filter 2 (mg/filter)	Filter 3 (mg/filter)	Filter 4 (mg/filter)	Filter 5 (mg/filter)	Filter 6 (mg/filter)	Filter 7 (mg/filter)	Filter 8 (mg/filter)	Filter 9 (mg/filter)	Filter 10 (mg/filter)
050	Male	Week 1	0.20	0.31	0.30	0.21	0.27	0.40	0.32	0.58	0.28	0.30
		Week 2	0.30	0.95	0.55	0.38	0.58	0.39	0.33	0.45	0.59	QNS
		Week 3	0.40	0.37	0.28	0.32	0.23	0.28	0.50	0.22	0.28	0.36
		Week 6	0.20	0.33	0.33	0.52	0.42	0.22	0.20	0.32	0.30	0.71
052	Male	Week 1	0.80	0.61	0.72	1.10	0.61	1.00	0.96	0.61	0.86	0.75
		Week 2	0.70	0.69	0.74	0.73	0.88	0.50	1.10	0.91	0.88	0.96
		Week 3	1.00	0.89	1.02	0.95	0.95	0.70	1.20	0.97	1.13	0.75
		Week 6	0.90	0.85	0.51	0.85	0.98	0.79	0.77	0.81	0.83	1.23
054	Male	Week 1	1.50	1.61	1.91	2.25	1.91	1.88	1.79	1.72	2.05	1.86
		Week 2	1.70	1.75	1.94	1.61	1.78	1.89	1.61	1.82	1.99	1.72
		Week 3	1.50	1.33	1.42	1.45	1.62	1.78	1.86	1.54	1.91	1.41
		Week 6	1.20	1.28	1.73	1.69	1.54	1.54	1.28	1.23	1.36	1.65
055	Male	Week 1	0.90	0.83	0.74	0.83	0.51	0.71	0.78	0.83	0.77	0.79
		Week 2	1.00	1.09	1.18	1.19	1.00	1.11	0.95	0.99	1.06	1.04
		Week 3	0.70	0.87	0.84	0.85	0.65	0.72	0.60	0.97	0.65	1.01
		Week 6	1.00	0.82	0.79	1.01	0.79	0.96	0.87	1.03	0.76	0.83
056	Male	Week 1	0.80	0.86	1.06	0.90	1.00	0.99	0.73	0.75	0.93	0.86
		Week 2	1.00	1.11	1.03	0.62	1.73	1.01	1.41	1.21	1.28	0.61
		Week 3	1.10	0.91	1.13	1.02	0.95	1.22	1.22	1.31	1.05	1.08
		Week 6	0.60	1.13	0.82	1.17	1.07	0.91	0.96	0.68	0.55	0.97
057	Male	Week 1	0.60	0.54	0.64	0.62	0.55	0.56	0.55	0.59	0.64	0.67
		Week 2	0.50	0.51	0.66	0.79	0.59	0.57	0.69	0.65	0.52	0.76
		Week 3	0.60	0.75	0.93	0.72	0.60	0.78	0.87	0.70	0.60	0.83
		Week 6	0.50	0.60	0.59	0.60	0.69	0.80	0.58	0.62	0.58	0.54
058	Male	Week 1	0.80	0.97	0.72	0.93	0.53	0.81	0.94	0.44	0.72	1.03
		Week 2	0.50	0.81	0.69	0.70	0.80	0.74	0.66	0.64	0.84	0.80
		Week 3	0.60	0.76	0.63	0.78	0.68	0.66	0.67	0.71	0.84	0.79
		Week 6	0.50	0.78	0.58	0.55	0.47	0.57	0.62	0.71	0.72	0.55

NOTE: QNS = Quantity not sufficient, NSR = No specimen received.

Listing 16.6-4
Nicotine from Cigarette Filters by Subject
(Page 9 of 10)

Subject Number	Gender	Timepoint	Filter 1 (mg/filter)	Filter 2 (mg/filter)	Filter 3 (mg/filter)	Filter 4 (mg/filter)	Filter 5 (mg/filter)	Filter 6 (mg/filter)	Filter 7 (mg/filter)	Filter 8 (mg/filter)	Filter 9 (mg/filter)	Filter 10 (mg/filter)
059	Male	Week 1	0.90	0.90	1.20	0.86	0.95	0.75	1.11	0.96	1.13	1.02
		Week 2	0.90	0.85	1.19	0.79	0.69	1.00	1.15	0.79	0.91	1.06
		Week 3	0.90	1.21	1.05	1.01	1.12	0.97	0.90	0.99	0.93	1.03
		Week 6	1.10	0.83	1.04	0.97	0.97	0.98	1.28	1.08	1.02	0.83
060	Male	Week 1	1.00	1.14	1.15	1.08	0.84	1.09	1.15	1.22	1.38	0.90
		Week 2	1.20	1.27	1.36	1.12	1.09	1.25	1.47	1.17	1.43	1.08
		Week 3	1.00	1.11	1.17	1.06	1.20	1.21	1.37	1.06	1.35	1.20
		Week 6	0.70	1.39	1.11	1.17	1.19	1.27	1.25	1.29	1.25	1.23
061	Male	Week 1	0.90	0.80	0.73	1.02	0.98	0.76	1.02	0.95	0.88	0.73
		Week 2	1.10	1.19	0.69	0.92	1.00	1.05	1.04	0.95	0.95	0.94
		Week 3	0.80	0.85	0.77	0.74	0.78	0.79	0.82	0.89	0.77	0.70
		Week 6	0.80	0.92	0.73	1.06	0.82	0.74	0.70	0.90	0.56	0.80
062	Male	Week 1	0.91	0.97	1.04	0.88	0.93	1.17	0.91	1.05	0.89	1.06
		Week 2	0.90	1.01	0.95	0.96	1.03	1.18	1.07	0.92	1.01	0.95
		Week 3	0.90	1.08	1.11	0.85	0.94	0.99	1.00	1.04	0.87	1.14
		Week 6	0.90	0.92	0.82	0.94	0.85	0.80	1.04	1.11	1.21	0.97
063	Male	Week 1	1.30	1.00	1.23	0.85	0.93	1.24	0.82	1.10	0.90	0.81
		Week 2	1.40	0.70	1.51	1.39	1.11	1.40	1.41	1.45	1.27	1.37
		Week 3	1.60	1.17	1.48	1.18	1.41	1.54	1.23	1.37	1.32	1.71
		Week 6	1.30	1.17	0.98	1.01	1.02	1.08	1.12	1.18	1.14	1.16
065	Male	Week 1	1.20	1.45	1.39	1.10	1.39	1.25	1.43	1.08	1.19	1.13
		Week 2	1.10	1.49	1.40	1.47	1.32	1.53	1.29	1.66	1.39	1.44
		Week 3	1.30	1.34	1.32	1.50	1.56	1.48	1.38	1.34	1.43	1.40
		Week 6	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR
067	Male	Week 1	0.10	0.21	0.15	0.10	0.20	0.10	0.16	0.15	0.14	0.17
		Week 2	0.20	0.15	0.18	0.15	0.13	0.11	0.19	0.28	QNS	QNS
		Week 3	0.30	0.28	0.36	0.32	0.18	0.19	0.25	0.34	0.43	0.29
		Week 6	0.30	0.43	0.43	0.47	0.50	0.41	0.34	0.36	0.36	0.35

NOTE: QNS = Quantity not sufficient., NSR = No specimen received.

Listing 16.6-4
Nicotine from Cigarette Filters by Subject
(Page 10 of 10)

Subject Number	Gender	Timepoint	Filter 1 (mg/filter)	Filter 2 (mg/filter)	Filter 3 (mg/filter)	Filter 4 (mg/filter)	Filter 5 (mg/filter)	Filter 6 (mg/filter)	Filter 7 (mg/filter)	Filter 8 (mg/filter)	Filter 9 (mg/filter)	Filter 10 (mg/filter)
068	Male	Week 1	0.60	0.81	0.66	0.81	0.62	0.66	0.52	0.57	0.65	0.80
		Week 2	0.50	0.47	0.58	0.76	0.64	0.70	0.53	0.82	0.34	0.81
		Week 3	0.70	0.70	0.70	0.78	0.92	1.15	0.81	0.92	0.79	0.72
		Week 6	0.50	0.51	0.59	0.77	0.64	0.63	1.03	0.96	0.48	0.67
069	Male	Week 1	0.60	0.70	0.70	0.64	0.57	0.94	0.76	0.54	0.69	0.76
		Week 2	0.87	0.66	0.65	0.71	0.62	0.80	0.55	0.93	0.69	0.66
		Week 3	0.80	1.03	0.73	0.94	0.84	0.69	0.49	0.83	0.92	1.05
		Week 6	0.90	0.76	0.93	0.82	0.76	0.63	0.75	0.76	0.79	0.84
502	Female	Week 1	0.80	0.98	1.09	1.22	1.04	1.26	1.06	1.44	0.83	1.50
		Week 2	1.00	1.51	1.13	1.29	1.19	1.11	1.12	1.25	1.03	1.29
		Week 3	1.00	1.06	1.24	1.16	1.23	0.96	1.21	1.26	0.90	1.11
		Week 6	1.00	0.96	0.85	0.85	0.86	1.13	0.99	1.18	0.95	0.97
503	Female	Week 1	0.80	0.92	0.89	0.86	0.90	0.78	0.77	0.88	0.81	0.81
		Week 2	0.80	0.83	0.80	0.65	0.90	0.94	0.82	0.86	0.84	0.86
		Week 3	0.70	0.34	0.54	0.57	0.39	0.51	0.66	0.50	0.59	0.34
		Week 6	0.60	0.94	0.60	0.80	0.70	0.71	0.67	0.67	0.65	0.61
504	Female	Week 1	1.20	1.41	1.09	1.37	1.47	1.52	1.61	1.37	1.21	1.27
		Week 2	1.10	1.15	1.29	1.14	1.25	1.21	1.29	0.92	1.10	1.36
		Week 3	1.20	1.47	1.07	1.04	1.08	1.54	1.04	1.11	1.22	1.15
		Week 6	0.80	1.01	0.89	0.92	0.75	0.80	0.68	0.80	0.83	0.88
506	Female	Week 1	0.40	0.52	0.67	0.54	0.51	0.30	0.52	0.44	QNS	QNS
		Week 2	0.60	0.56	0.90	QNS	QNS	QNS	QNS	QNS	QNS	QNS
		Week 3	0.60	0.72	0.65	0.81	0.71	0.75	0.76	0.64	0.66	0.64
		Week 6	0.40	0.45	0.48	0.45	0.35	0.49	0.47	0.48	0.48	0.54

NOTE: QNS = Quantity not sufficient., NSR = No specimen received.

Listing 16.6-5
Fagerström Tolerance Test Results for Smokers by Subject
(Page 1 of 2)

Subject Number	Subject Classification ^a	Result
001	F-S	8 - 10: Very high dependence
002	F-S	3 - 4: Low dependence
003	F-S	0 - 2: Very low dependence
004	F-S	3 - 4: Low dependence
005	F-S	0 - 2: Very low dependence
006	F-S	6 - 7: High dependence
007	F-S	0 - 2: Very low dependence
008	F-S	3 - 4: Low dependence
009	F-S	3 - 4: Low dependence
010	F-S	0 - 2: Very low dependence
011	F-S	5: Medium dependence
012	F-S	6 - 7: High dependence
013	F-S	3 - 4: Low dependence
014	F-S	5: Medium dependence
015	F-S	0 - 2: Very low dependence
016	F-S	3 - 4: Low dependence
017	F-S	5: Medium dependence
018	F-S	0 - 2: Very low dependence
019	F-S	0 - 2: Very low dependence
020	F-S	6 - 7: High dependence
021	F-S	0 - 2: Very low dependence
022	F-S	5: Medium dependence
023	F-S	5: Medium dependence
024	F-S	0 - 2: Very low dependence
025	F-S	3 - 4: Low dependence
026	F-S	6 - 7: High dependence
027	F-S	3 - 4: Low dependence
028	F-S	3 - 4: Low dependence
029	F-S	5: Medium dependence
030	F-S	3 - 4: Low dependence
031	F-S	0 - 2: Very low dependence
032	F-S	0 - 2: Very low dependence
033	F-S	0 - 2: Very low dependence
034	F-S	3 - 4: Low dependence
035	F-S	5: Medium dependence
036	M-S	3 - 4: Low dependence
037	M-S	0 - 2: Very low dependence
038	M-S	5: Medium dependence

NOTE: Results are calculated from Question 3.39 through Question 3.44 from the Enrollment Questionnaire.

^a Subject Classification: M-S=Male, Smoker; F-S=Female, Smoker.

PM3006630478

Listing 16.6-5
Fagerström Tolerance Test Results for Smokers by Subject
(Page 2 of 2)

Subject Number	Subject Classification ^a	Result
039	M-S	3 - 4: Low dependence
040	M-S	0 - 2: Very low dependence
041	M-S	6 - 7: High dependence
042	M-S	3 - 4: Low dependence
043	M-S	5: Medium dependence
044	M-S	3 - 4: Low dependence
045	M-S	3 - 4: Low dependence
046	M-S	3 - 4: Low dependence
047	M-S	0 - 2: Very low dependence
048	M-S	0 - 2: Very low dependence
049	M-S	5: Medium dependence
050	M-S	3 - 4: Low dependence
051	M-S	0 - 2: Very low dependence
052	M-S	0 - 2: Very low dependence
053	M-S	5: Medium dependence
054	M-S	6 - 7: High dependence
055	M-S	8 - 10: Very high dependence
056	M-S	6 - 7: High dependence
057	M-S	5: Medium dependence
058	M-S	3 - 4: Low dependence
059	M-S	6 - 7: High dependence
060	M-S	3 - 4: Low dependence
061	M-S	6 - 7: High dependence
062	M-S	6 - 7: High dependence
063	M-S	3 - 4: Low dependence
065	M-S	3 - 4: Low dependence
066	M-S	6 - 7: High dependence
067	M-S	0 - 2: Very low dependence
068	M-S	3 - 4: Low dependence
069	M-S	8 - 10: Very high dependence
502	F-S	0 - 2: Very low dependence
503	F-S	5: Medium dependence
504	F-S	6 - 7: High dependence
506	F-S	0 - 2: Very low dependence

NOTE: Results are calculated from Question 3.39 through Question 3.44 from the Enrollment Questionnaire.

^a Subject Classification: M-S=Male, Smoker; F-S=Female, Smoker.